Lewis Stein, Esq.
NUSBAUM, STEIN,GOLDSTEIN,
BRONSTEIN & KRON, P.A.
20 Commerce Boulevard, Suite E
Succasunna, NJ 07876
nsgbk.office@verizon.net
(973) 584-1400
Attorneys for Plaintiffs

UNITED STATES DISTRICT COURT
for the
DISTRICT OF NEW JERSEY

CHAYA GROSSBAUM and MENACHEM GROSSBAUM, her spouse, individually and as *guardians ad litem* of the infant ROSIE GROSSBAUM,	
Plaintiffs,	CIVIL ACTION NO. 07-CV-1359 (GEB)
vs.	
GENESIS GENETICS INSTITUTE, LLC, of the State of Michigan, MARK R. HUGHES, NEW YORK UNIVERSITY SCHOOL OF MEDICINE and NEW YORK UNIVERSITY HOSPITALS CENTER, both corporations in the State of NEW YORK, ABC CORPS. 1-10, JOHN DOES 1-10,	
Defendants.	

CERTIFICATION OF LEWIS STEIN, ESQ.

1. I am an attorney at law in the State of New Jersey having been admitted to practice in the United States District

Court for the District of New Jersey in 1961. I have been the sole attorney who has been involved in the processing of this litigation on behalf of the Plaintiffs.

2. By facsimile and regular mail dated February 26, 2010 I received a letter from Stephen N. Leuchtman, counsel to the Defendant, Genesis Genetics (see copy annexed hereto as Exhibit A), enclosing the report of "Kangpu Xu, Ph.D." (see copy of report annexed hereto as Exhibit B).

3. Subsequently, by fax on March 4th, I received a letter from Mr. Leuchtman (see copy of letter annexed hereto as Exhibit C) enclosing the expert report of Dr. Mark Hughes dated March 2, 2010 (see copy of report annexed hereto as Exhibit D).

4. Upon review the reports of Dr. Xu and Hughes revealed a substantial amount of identical paragraphs and, within other paragraphs, identical sentences and even identical misplaced punctuation. See copy of Dr. Kangpu Xu's expert report of February 26th with bolded sections of identical language also found in Dr. Hughes' report of March 2nd. See copies of both Dr. Xu's and Hughes' bolded reports annexed hereto as Exhibits E and F respectively.

5. Further idiosyncrasies in Dr. Xu's report are found in the biographical paragraph located at the bottom of Page 1 of his report where there are numerous syntactical mistakes on almost every line that do not similarly appear in that part of

the report where opinions and comments are made with regard to the medical principles to be applied to the facts of the case.

6. The similarities between the two experts' reports on behalf of Defendant Genesis Genetics were the subject of investigation at the depositions of both Drs. Xu and Hughes.

7. Dr. Xu in his deposition gave testimony that: "English is a second language to him (T33-18); he left China at age 31 (T:34-3); he came to Canada sometime around 1987 and did not return to China thereafter (T:33-20 to 34:6). He did not have any assistance in preparing the report, except he discussed a few points with Mr. Leuchtman, but he wrote the report himself. (T:34-7) He denied ever speaking to Dr. Hughes about the report or the case. (T:34-11 to 34-16) The report was prepared on a computer typed by himself. (T:36-4 to 36-16) When the syntactical curiosities in the biographical paragraph were pointed out to Dr. Xu, he stated that he was not native to the English language (T:40-7), and did not seek editorial help which he usually does with his publications since he believed his letter to be confidential. (T:40-13) See copy of Dr. Xu's deposition transcript annexed hereto as Exhibit G.

8. The aforementioned characteristics of Dr. Xu's report dated February 26th, which incidentally was forwarded to the Plaintiff by Mr. Leuchtman by letter dated the same day as the date of the report, leave open the question as to whether Dr.

Xu's report was prepared by the defense in this case with all of the implications that that fact bears.

9. Dr. Hughes' deposition as an expert offered on behalf of himself, which is annexed hereto as Exhibit H, took place on May 14, 2010 in Detroit. Dr. Hughes had previously been deposed as a defendant on February 19, 2009.

10. When presented with his report of March 2, 2010, Dr. Hughes stated, "I didn't write it, but I saw it." (T:6-2) When asked, "Is that your signature, Doctor?" He answered, "Yep. Well, I didn't sign it with my hand, that's an electronic one, but yes." (T:6-5 to 6-7) That testimony begets a further inquiry since Dr. Hughes' handwritten signature appears in the Genesis Genetics records previously provided to the Plaintiff at Page 4 and 5 of his initial consultation. It is respectfully submitted that a real question exists as to why the signature looks as it does on the report as compared to the signature that was contained in the Genesis Genetics record.

11. When asked, "Well, if you didn't write it, could you tell me who wrote it?" The witness then turned to his lawyer, Stephen Leuchtman, and stated, "Because you [Mr. Leuchtman] did it..." (T:6-10) He went on to claim that he was traveling and that Leuchtman emailed him a draft of the report which he subsequently edited and electronically signed and sent back to Leuchtman. (T: 6-13 to 6-23) Specifically to Leuchtman he said,

"You wrote the stuff and I edited it." (T:6-19) The witness added further, "It's not exactly the way I would have written it." (T:6-25 to 7-1) Dr. Hughes repeated again spontaneously, facing Leuchtman, "Because I didn't write this, I didn't actually write this." (T:7-13 to 7-14)

12. There followed an inappropriate interruption of the testimony by both Mr. Leuchtman and Mr. Hamad, attorney for the Defendant NYU. That was the first of at least 20 inappropriate interruptions by either Mr. Leuchtamn or Mr. Hamad during the course of an 80 page deposition. This will be the subject of further discussion.

13. A recess was requested by defense counsel, which lasted more than 20 minutes. Upon return, Mr. Leuchtman stated, "I am going to instruct Dr. Hughes not to answer any further questions about how the report came into existence." (T:18-11 to 18-13) Further efforts to inquire about the email transmittals and its availability were not answered. See Pages 18 and 19 of Dr. Hughes' deposition transcript marked as Exhibit H.

14. In addition, provided with the report was a two page biography of Dr. Hughes which appeared to be intended to serve as his *curriculum vitae* (see copy annexed hereto as Exhibit I). When the witness was confronted with the two page biography, Dr. Hughes stated, "I do not know where this exactly came from." He indicated that that biography was also not written by him, but

by someone else unknown to him. (T:21-1)

15. Mr. Leuchtman was advised by the undersigned that it was my intention to seek his testimony as a fact witness to the creation of Dr. Hughes' expert report. During the further course of his deposition, Dr. Hughes indicated that the report contained statements that he did not agree with. He expressly disclaimed agreement with a sentence made in the second to last paragraph of his report which read: *Based on the literature, most misdiagnoses are due to intercourse or unprotected sex.* Asked if he agreed with that, he said, "No." (T:78-6 to 78-9)

16. Dr. Hughes also acknowledged another incorrect statement in what purported to be his letter report. At Page 40 of his deposition transcript, he disclaimed the validity of a statement that read: *I have had people over the years voice objection to amino or CVS and when this has happened I have referred them to organizations who did not require conventional prenatal follow-up testing with amnio or CVS."* (T:40-7 to 40-19)

17. In addition, Defendant Hughes surprised both the undersigned, counsel for the Plaintiff, and counsel for NYU when he stated in his deposition for the first time that the document contained in Genesis Genetics' records (T:62-4 to 62-19) and found in the NYU records was in fact not a document created by him and the electronic signature attached to the record was not affixed by him, but by some other member of the Genesis Genetic

staff. Moreover, this document, which had been previously identified during the course of NYU's deposition testimony as being the only report from Genesis Genetics, was now characterized by Dr. Hughes in his deposition that the above mentioned report form "was not the standard form by which Genesis Genetics reports the results of its testing." (T:58-1) The report was described as a "temp report early as quickly as we have the data." Subsequent to sending the report, marked as Exhibit J, according to Dr. Hughes, Dr. Hughes or one of his staff sits down and writes a formal report. (T:59-7 to 59-9) This "formal report", which report appears in the Genesis Genetics' records, was not found in the NYU chart. At all times during the depositions of the NYU staff (Dr. Licciardi, Dr. Grifo and embryologist Alexis Adler, as well as in the first deposition of Dr. Hughes, there was no indication that the document marked as Exhibit J, was either not electronically signed by Dr. Hughes and was to be considered only a temporary or interim report.

18. One of the critical fact issues in this case is whether a genetic study of the patient's embryos was available that would reduce or eliminate the risk of having an affected baby. One such process is described as "linkage analysis" in the laboratory study. When confronted with the literature indicating that that process was well known as of publications

in 2001, Dr. Hughes reported that "they [the publishers] were taking two cells in order to get those results so they were biopsying a couple of cells from each embryo. Most of the clinics we work with don't want to do that including NYU." (T:47-13 to 47-16) This is new testimony and becomes a fact issue of considerable importance.

19. In addition, that issue became the subject of inquiry in Dr. Kangpu Xu's deposition. Dr. Xu stated at one point, "We started to do—tried to do linkage analysis in early 2000." (T:27-13) He elaborated that he thought that he was not really sure whether it was in the year 2000. He elaborated further that "It was—well, it started in the beginning of 2000. I can't be 100%—I can't be 100% sure." (T:28-16) When asked specifically the following question, Dr. Xu answered as follows:

> Q. IS IT YOUR TESTIMONY THAT NO LINKAGE ANALYSIS WAS DONE AT YOUR LABORATORY FOR CYSTIC FIBROSIS PRIOR TO 2000?
> A. I CAN'T BE SURE BUT IT'S LIKELY.
>
> (T:28-19 to 28-22)

20. He followed that up with what seemed to be an entirely inconsistent answer in response to the next question:

> Q. OKAY. IS IT YOUR TESTIMONY UNDER OATH THAT NO CYSTIC FIBROSIS ANALYSIS WAS DONE USING LINKAGE PROCEDURES IN CYSTIC FIBROSIS PRIOR TO 2004?
> A. IN MY LAB?
> Q. YES.
> A. THAT WILL BE TRUE. THAT WILL BE CORRECT. YES.
> Q. OKAY. WHEN IS THE FIRST OCCASION THAT YOU USED LINKAGE ANALYSIS FOR A CYSTIC FIBROSIS MUTATION?

A. MID 2000. MID 2000, I WOULD SAY.
Q. WHEN YOU SAY "MID 2000," WHAT YEAR ARE YOU REFERRING TO?
A. I DON'T REMEMBER EXACTLY WHAT YEAR UNLESS I GO BACK TO LOOK AT OUR LAB RECORDS.
Q. OKAY. IS IT POSSIBLE THAT YOU WERE DOING LINKAGE ANALYSIS IN 2004?
MR. LEUCHTMAN: PRIOR TO 2004?
Q. YES.

(T:28-23 to T:29-14)

The pursuit of this factual information would appear to be a critical fact in the entire case.

I certify that the foregoing statements made by me are true. I am aware that if any of the foregoing statements made by me are willfully false, I am subject to punishment.

Date: June 2, 2010

Signature of Attorney

Lewis Stein, Esq.
Printed name

20 Commerce Blvd., Suite E
Succasunna, NJ 07876
Address

nsgbk.office@verizon.net
E-mail address

(973) 584-1400
Telephone number

EXHIBIT A

Stephen N. Leuchtman, P.C.
1380 E. Jefferson Ave. Detroit, Mi 48207
Tel: (313) 259-6900, ext. 126
Fax: (313) 259-3474
leuchlaw@gmail.com

February 26, 2010

BY FACSIMILE & REGULAR MAIL

Lewis Stein, Esq.
Nusbaum, Stein, Goldstein,
Bronstein & Kron
20 Commerce Blvd.
Succasunna, NJ 07876

R. Scott Eichhorn, Esq.
Marshall, Dennehy, Warner, Coleman & Goggin, P.C.
425 Eagle Rock Avenue, Suite 302
Roseland, NJ 07068

Sarah Blaine, Esq.
Lowenstein Sandler
65 Livingston Avenue
Roseland, NJ 07068

RE: **Grossbaum v. Genesis Genetics Institute et al.**
Case # 07–CV–1359 (HAA)

Dear Counsel:

Enclosed herewith please find the report of Kangpu Xu, PhD, HCLD, in compliance with the Court's most recent Scheduling Order. His CV will follow under separate cover.

Very truly yours,

Stephen N. Leuchtman

Enclosures

EXHIBIT B

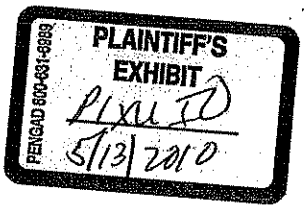
Weill Cornell Medical College

NewYork-Presbyterian Hospital
Weill Cornell Medical Center

Kangpu Xu, Ph.D.
Director, Laboratory of Preimplantation Genetics
Associate Professor

The Center for Reproductive Medicine and Infertility
1300 York Avenue, P.O. Box 30
New York, NY 10065

Telephone: 212-746-6301
Fax: 212-746-8589
E-mail: kpxu@med.cornel.edu



February 26, 2010

Stephen N. Leuchtman, P.C.
1380 E. Jefferson Ave.
Detroit, MI 48207

RE: Grossbaum v. Genesis Genetics & Hughes

Dear Mr. Leuchtman,

Per your request, I have reviewed the following documents which you sent to me:

1) Medical Records of Genesis Genetics
2) Medical Records of IVF Center of New York University Medical Center
3) Reports from Dr. Garry R, Cutting and Dr. Charles M. Strom
4) Depositions of Mark R. Hughes, MD, PhD, Genesis Genetics; and Frederick Licciardi, MD, James Grifo, MD, PhD; Ms Alexis Adler, Kaycian Brown, R.N.; and Ms. Imelda Weill, New York University Medical Center
5) Depositions of Chaya Grossbaum (Volume 1 and 2) and Menachem M. Grossbaum.

As I understand, both Chaya Grossbaum and Menachem M. Grossbaum are carriers of a mutation for cystic fibrosis gene. They were referred to NYU IVF center and underwent IVF and biopsy at NYU and the specimens were sent and analyzed by Genesis Genetics. The child born from the procedure was found be affected with cystic fibrosis.

As you probably know, I have been involved in PGD since 1992 when I was recruited as a faculty member at Cornell Medical College. I have published number of papers in PGD. For example, in 1993 we studied a new procedure, call Primer Extension Preamplification (PEP) for single human blastomeres. In particular we tested the most common CF mutation, delta F508, in the amplified products (Human Reproduction, 1993vol.8, No.12, pp2206-2210). In 1999, we published the first successful PGD case for sickle cell anemia (JAMA). Again in 2004, first PGD for retinoblastoma was reported in American Journal of Ophthalmology. Furthermore, I am a certified laboratory directory by ABB (American Board of Bioanalysis) since 2002 and by New York State Department of Health as laboratory director since Oct. 5, 2004. My laboratory, Laboratory of Preimplantation Genetics, Center for Reproductive Medicine and Infertility, Weill Medical College of Cornell University, obtained permit for performing PGD for molecular testing since March 2006 and for

cytogenetics, since 2007. Beginning from 1995, as I was the head of the PGD program and later as the director of the laboratory at the Center for Reproductive Medicine and Infertility, Weill Cornell Medical College. We have completed over 1300 cases of PGD for variety of indications, including more than 70 cases for cystic fibrosis, covering more than a dozen of CF mutations.

Having known Dr. Mark Hughes as many years as I have been involved in PGD, he is, without any doubt, one of the most renowned pioneers in Preimplantation Genetic Diagnosis. He was the coauthor of the very first paper in the scientific literature described the success of PGD for cystic fibrosis (1992, New England Journal of Medicine). He was a member of President Bioethics Council that described the importance of PGD and recommended funding for PGD research in 1994. It is definitely not trivial that he was recognized and highly praised by the Jewish community, Bonei Olem, for his contribution to PGD (see Dr. Licciardi's deposition, page 25).

An open question and a central issue in PGD is that PGD has its limitations because it is a single cell based test. It has been recognized in the beginning of last decade in the PGD community that allele drop out (ADO), which occurs when low DNA copy numbers are used as the starting material for genetic testing, is a challenging issue. Numerous papers have been published in order to reduce or eliminate this inherent risk. Some proposed to biopsy two cells from one embryo, others tested different lysis strategies; still others were trying to use whole genome amplification to obtain more DNA for replicate testing. None of them appears to be fully effective. Current understanding is that ADO is a very complicated matter and there may be many contributing factors. ADO varies from cell type to cell type. ADO is usually low in the healthy cells, such as lymphocytes and fibroblast cells harvested at the growth phase. Likewise in blastomeres, ADO may also vary according the healthy status of the cells/embryos. It is not unreasonable that a healthy diploid blastomere (D3, 7-9 cell stages) provide lowest chance of ADO. Indeed, we have seen more aneuploidy/mosaicism in those slow developing or arrested embryos (4-5 cells on the morning of Day-3 post fertilization) in our FISH based aneuploidy tests.

Accumulated knowledge from the Human Genome Project facilitates the use of linkage markers which may reduce substantially the risk of ADO. Though it is highly desirable, markers are not always used even as of today for various reasons. Finding informative linkage markers is not trivial task or an overnight procedure. Building whole sets of linkage markers for each disorder/mutation is a continuing process. In 2004, not all the laboratories were using linkage markers and not for every single mutation; in other words, multiplex PCR was not the standard in 2004. During a period from 2001 to 2005, we successfully performed PGD for RB, an autosome dominant disorder with 50% risk without using markers. The reason was not that we were ignorant, but with the limitation that we had because we could not find markers that were informative for the couple. Three healthy singletons were born from 4 diferent IVF-PGD attempts. I believe tests conducted by Dr. Hughes were proper, appropriate and within the standard of practice existing at the time for this couple.

The tests performed on July 18-19, 2004 did statistically reduce the risk, from 25% to a much lower percentage. It was proper to recommend the transfer of embryo #7 and 8 based upon both reports issued by Dr. Hughes and Genesis Genetics on July 19, 2004. Results in both of Dr. Hughes' reports prepared on July 19, 2004 were within the accepted level of risk and the level of risk agreed to by the patients.

Another issue of embryological work using polar body biopsy is open for debate. Polar body biopsy or preconception genetic diagnosis was reported in 1990. However, the use of polar body biopsy has been limited in a few laboratories around the world. A few laboratories that performing polar body biopsy, such as those in Germany and Italy, not because of its superior strategy but because of their

country's law. As of today polar body biopsy for PGD is yet to be a mainstream approach (see a most recent debate article by Geraedts et al. Human Reproduction, 2010, v25, pp575). It was not its technical difficult, but with its real benefits in routine PGD. If one looks ESHRE (European Society of Human Reproduction and Embrylogy) data collection from I to IX (the latest one), one could only find few cases PGD using polar bodies as testing materials. At CRMI, we performed PB biopsy in the late 90's for balanced translocation; the girl is now over 12 year old. Nevertheless, we have not, as most of the labs in the world, used PB biopsy as a routine procedure.

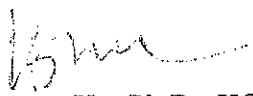
Because of the ever-present risk of ADO, and other risk factors inherent in PGD, CVS and amniocentesis are universally relied upon as a safety net in PGD. CVS has been shown to be very accurate. I know from my experience that Dr. Hughes and Genesis Genetics will not take on PGD of a couple if they will not agree in advance to CVS or amniocentesis; and this is appropriate and within accepted standards.

From the documents I reviewed I believe that the couple was well informed on many occasions that there were risks of misdiagnosis and they have signed at least two important PGD consents, one from NYU, and one from Hughes' team. Dr Hughes went all the details, as much as he could, with the couple. Specifically, and without going into every detail in the consent forms, the Grossbaums demonstrated an understanding that this is not a perfect technology, it is complicated, it is an experimental process, lowering the risk to zero is not realistic or possible, the technology can fail, and follow-up confirmation testing (in the form of CVS or amniocentesis) is necessary. The Grossbaums agreed to go forward in light of the risks and alternatives, and they agreed with both NYU and Genesis Genetics to undergo confirmation testing in the form of CVS or amniocentesis.

Because of so many variables involved in PGD, the cause(s) of PGD misdiagnosis is always difficult to pin down. Based on the literature most misdiagnosis is due to intercourse or unprotected sex. In a published data collection (ESHRE PGD consortium data collection VII: cycles from January to December 2004 with pregnancy follow-up to October 2005, Human Reproduction, 2008; Vol 23, No. 4, pp 741755), the best data collection and analysis in PGD community, the consortium stated on page 750 that "Eighteen misdiagnosis have been reported, 9 after PGD for PCR and 9 after PGD or PGS using FISH. In all cases of misdiagnosis, unprotected sex during the PGD cycle could be responsible as any embryos generated in vivo would not be tested." With this in mind, it is speculation to say that the bad result in this case was caused by the implantation of an affected embryo, as opposed to any of a number of other causes, including intercourse or unprotected sex by the Grossbaums.

In summary, I see a tragic case happened, not because of any negligence, but unfortunately because of the complexity and the limitations of the PGD technology and likely other confounding factors. Genesis Genetics did very professionally, and no deviations were seen from the standard of care.

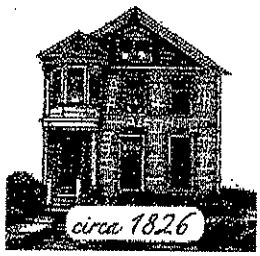
Respectfully yours,



Kangpu Xu, Ph.D., HCLD.
Associate Professor
Director, Laboratory of Preimplantation Genetics
CRMI, Weill Cornell Medical College

EXHIBIT C

Stephen N. Leuchtman, P.C.
1380 E. Jefferson Ave. Detroit, MI 48207
Tel: (313) 259-6900, ext. 126
Fax: (313) 259-3474
leuchlaw@gmail.com



March 3, 2010

BY FACSIMILE & REGULAR MAIL

Lewis Stein, Esq.
Nusbaum, Stein, Goldstein,
Bronstein & Kron
20 Commerce Blvd.
Succasunna, NJ 07876

R. Scott Eichhorn, Esq.
Marshall, Dennehy, Warner, Coleman & Goggin, P.C.
425 Eagle Rock Avenue, Suite 302
Roseland, NJ 07068

Sarah Blaine, Esq.
Lowenstein Sandler
65 Livingston Avenue
Roseland, NJ 07068

RE: **Grossbaum v. Genesis Genetics Institute et al.**
Case # 07-CV-1359 (HAA)

Dear Counsel:

Enclosed herewith please find the report of Mark R. Hughes, M.D., PhD, and two resumes of his qualifications, in compliance with the Court's most recent Scheduling Order.

Very truly yours,

Stephen N. Leuchtman

Enclosures

EXHIBIT D

genesis
genetics institute

March 2, 2010

Stephen N. Leuchtman, P.C.
1380 E. Jefferson Ave.
Detroit, MI 48207

RE: Grossbaum v. Genesis Genetics & Hughes

Dear Mr. Leuchtman,

As this case has progressed, I have been provided with and have read the following materials:

1) Medical Records of Genesis Genetics
2) Medical Records of IVF Center of New York University Medical Center
3) Reports from Dr. Garry R, Cutting and Dr. Charles M. Strom
4) Depostions of Mark R. Hughes, MD, PhD, Genesis Genetics; and Frederick Licciardi, MD, James Grifo, MD, PhD; Ms Alexis Adler, Kaycian Brown, R.N.; and Ms. Imelda Weill, New York University Medical Center
5) Depostions of Chaya Grossbaum (Volume 1 and 2) and Menachem M. Grossbaum.

Both Chaya Grossbaum and Mechachem Grossbaum are carriers of a mutation for cystic fibrosis gene. They were referred to NYU IVF center and underwent IVF and biopsy at NYU and the specimens were sent and analyzed by Genesis Genetics. The child born from the procedure was found be affected with cystic fibrosis.

I spoke with the Grossbaums on March 25, 2004 and explained to them in detail what was going to happen in the course of preimplantation genetic diagnosis (PGD). I explained that the technology involved is imperfect and pushes medical diagnostic technology to its absolute limit, its practical limit and its theoretical limit. I explained that PGD technology is in fact an experimental process, and that the technology can fail. I explained that the risk of natural pregnancy was that there was one chance in four that the baby would be afflicted with cystic fibrosis, whereas that risk could be significantly lowered by PGD, but not eliminated. Each test for the cystic fibrosis mutation(s) is custom-designed, so it is extremely difficult to predict the chances of success in any given implantation following PGD. I advised people in 2004 that the risk of having an affected child is three to five percent, and I am certain I imparted this to the Grossbaums.

Further, Genesis Genetics and I will not perform PGD for a couple who does not agree in advance to

Genesis Genetics Institute, LLC
5555 Conner, Suite 1100
Detroit, MI 48213
313-579-9650 313-544-4006 fax
GenesisGenetics.org

undergo chorionic villus sampling (CVS) or amniocentesis (amnio) early in the pregnancy. CVS is typically done at around ten weeks, and amnio is usually done at fifteen to sixteen weeks. I made the necessity of undergoing CVS or amnio known to the Grossbaums, and they agreed to this condition. At no time did they voice any objection or problem to me about CVS or amnio. Had they made any such objection, I would not have taken their case; and this fact was well known to NYU. I have had people over the years voice objections to amnio or CVS; and when this has happened, I have referred them to organizations who did not require conventional prenatal follow-up testing with amnio or CVS. It has always been an absolute, fully agreed upon, prior requirement of our program.

After the Grossbaums were informed about information including all of the above and more, they advised that they had no questions and were satisfied with what was going to be done. In may, 2004, I sent them a Preimplantation Genetic Diagnosis Patient Informed Consent, which the Grossbaums signed on June 4, 2004 and I countersigned on July 16, 2004. this Informed Consent included the following language, to which the Grossbaums agreed: "between ten and fifteen weeks of pregnancy you will undergo conventional prenatal genetic testing in the form of chorionic villus sampling (CVS) or amniocentesis. The sample will be used to confirm the predicted PGD test results." Based upon this written agreement following the oral agreement on March 25, 2004, I went ahead with PGD for this couple. My review of the NYU records and the depositions of the NYU people confirms that at no time did the Grossbaums ever voice any reservations to NYU about undergoing CVS or amnio.

As Dr. Kangpu Xu has pointed out in his report, an open question and a central issue in PGD is that PGD has its limitations because it is a single cell based test. It has been recognized since the beginning of last decade in the PGD community that allele drop out (ADO), which occurs when low DNA copy numbers are used as the starting material for genetic testing, is a challenging issue. Numerous papers have been published in order to reduce or eliminate this inherent risk. Some proposed to biopsy two cells from one embryo, others tested different lysis strategies, still others were trying to use whole genome amplification to obtain more DNA for replicate testing. Current understanding is that ADO is a very complicated matter and there are may be many contributing factors. ADO varies from cell type to cell type. ADO is usually low in the healthy cells, such as lymphocytes and fibrolast cells harvested at the growth phase. Likewise in blastomeres, ADO may also vary according the healthy status of the cells/embryos. It is not unreasonable that a healthy diploid blastomere (D3, 7-9 cell stages) provide lowest chance of ADO.

The use of linkage markers in 2004 for cystic fibrosis mutations was not standard of care in the field of PGD. Multiplex testing was done at the time in some laboratories for some diseases, but it was very new and experimantal in early 2004, including when the Grossbaums underwent PGD and IVF. Even today for various reasons, these procedures are not in universal use. Finding informative linkage markers is not trivial task or an overnight procedure. As Dr. Kangpu Xu has pointed out, building whole sets of linkage markers for each disorder/mutation is a continuing process. In 2004, not all the laboratories were using linkage markers and not for every single mutation; in other words, multiplex PCR was not the standard in 2004. I believe the tests conducted by my lab and myself were proper, appropriate and within the standard of practice existing at the time for this couple.

The tests performed on July 18-19, 2004 statistically reduced the risk, from 25% to much a much lower percentage. It was proper to recommend the transfer of embryo #7 and 8 based upon both

reports issued by myself and Genesis Genetics. I prepared two reports on July 19. One was somewhat abbreviated; and the other went into greater detail. The results in both of my reports prepared on July 19, 2004 were within the accepted level of risk and the level of risk agreed to by the patients.

When I biopsy cells, I can comment to a degree on the likelihood that they will be affected or carriers of the disease we are looking for; but I cannot comment on the condition of the embryos on the day of implantation. Ultimately, the decision to go forward is that of the couple involved based on the best information their doctor and my lab and I can impart to them as of the day of implantation or transfer.

Dr. Kangpu Xu addresses polar body biopsy at great length in his expert report. I agree with his conclusions.

As allluded to above, because of the ever-present risk of ADO, and other risk factors inherent in PGD, CVS and amniocentesis are universally relied upon as a safety net in PGD. It was within the applicable standard of care for my lab and myself to insist upon agreement to CVS or amniocentesis as a condition to doing PGD. The Grossbaums agreed to go forward in light of the risks and alternatives, and they agreed with both NYU and Genesis Genetics to undergo confirmation testing in the form of CVS or amniocentesis.

As was pointed out by Dr. Kangpu Xu, because of so many variables involved in PGD, the causes of PGD misdiagnosis are always difficult to pin down. Based on the literature most misdiagnoses are due to intercourse or unprotected sex. In a published data collection (ESHRE PGD consortium data collection VII: cycles from January to December 2004 with pregnancy follow-up to October 2005, Human Reproduction, 2008; Vol 23, No. 4, pp 741755), the best data collection and analysis in PGD community, the consortium stated on page 750 that "Eighteen misdiagnosis have been reported, 9 after PGD for PCR and 9 after PGD or PGS using FISH. In all cases of misdiagnosis, unprotected sex during the PGD cycle could be responsible as any embryos generated in vivo would not be tested." With this in mind, it is speculation to say that the bad result in this case was caused by the implantation of an affected embryo, as opposed to any of a number of other causes, including intercourse or unprotected sex by the Grossbaums.

In summary, I believe that the unfortunate result in this case occurred, not because of any negligence, but unfortunately because of the complexity and the limitations of the PGD technology and likely other confounding factors. We acted professionally and at all times consistently with the standard of care as it existed at the time.

Very truly yours,

Mark R. Hughes

Mark R. Hughes

EXHIBIT E

Weill Cornell Medical College

New York-Presbyterian Hospital
Weill Cornell Medical Center

Kangpu Xu, Ph,D,
Director, Laboratory of Preimplantation Genetcs
Associate Professor

The Center for Reproductive Medicine and Infertility
1300 York Avenue, P.O. Box 30
New York, NY 10065

Telephone: 212-746-6301
Fax: 212-746-8589
kpxumed.cornell.edu

February 26, 2010

Stephen N. Leuchtman, P.C.
1380 E. Jefferson Ave.
Detroit, MI 48207

RE: Grossbaum v. Genesis Genetics & Hughes

Dear Mr, Leuchtman,

Per your request, I have reviewed the following documents which you sent to me:

1) Medical Records of Genesis Genetics
2) Medical Records of IVF Center of New York University Medical Center
3) Reports from Dr. Garry R, Cutting and Dr. Charles M. Strom
4) Depositions of Mark R. Hughes, MD, PhD, Genesis Genetics; and Frederick Licciardi, MD, James Grifo, MD, PhD; Ms Alexis Adler, Kaycian Brown, R.N.; and Ms. Imelda Weill, New York University Medical Center
5) Depositions of Chaya Grossbaum (Volume 1 and 2) and Menachem M. Grossbaum.

As I understand, **both Chaya Grossbaum and Menachem M. Grossbaum are carriers of a mutation for cystic fibrosis gene. They were referred to NYU IVF center and underwent IVF and biopsy at NYU and the specimens were sent and analyzed by Genesis Genetics. The child born from the procedure was found be affected with cystic fibrosis.**

As you probably know, I have been involved in PGD since 1992 when I was recruited as a faculty member at Cornell Medical College. I have published number of papers in PGD. For example, in 1993 we studied a new procedure, call Primer Extension Preamplification (PEP) for single human blastomeres. In particular we tested the most common CF mutation, delta F508, in the amplified products (Human Reproduction, 1993vo1.8, No.12, pp2206-2210). In 1999, we published the first successful. PGD case for sickle cell anemia (JAMA). Again in 2004, first PGD for retinoblastoma was reported in American Journal of Ophthalmology. Furthermore, I am a certified laboratory directory by ABB (American Board of Bioanalysis) since 2002 and by New York State Department of Health as laboratory director since Oct. 5, 2004. My laboratory, Laboratory of Preimplantation Genetics, Center for Reproductive Medicine and Infertility, Weill Medical College of Cornell University, obtained permit for performing POD for molecular testing since March 2006 and for

cytogenetics, since 2007. Beginning from 1995, as I was the head of the PGD program and later as the director of the laboratory at the Center for Reproductive Medicine and Infertility, Weill Cornell Medical College. We have completed over 1300 cases of POD for variety of indications, including more than 70 cases for cystic fibrosis, covering more than a dozen of CF mutations.

Having known Dr. Mark Hughes as many years as I have been involved in PGD, he is, without any doubt, one of the most renowned pioneers in Preimplantation Genetic Diagnosis. He was the coauthor of the very first paper in the scientific literature described the success of POD for cystic fibrosis (1992, New England Journal of Medicine). He was a member of President Bioethics Council that described the importance of PGD and recommended funding for PGD research in 1994. It is definitely not trivial that he was recognized and highly praised by the Jewish community, Bonei Olem, for his contribution to PGD (see Dr. Liciardi's deposition, page 25).

An open question and a central issue in PGD is that POD **has its limitations because it is a single cell based test. It has been recognized** in **the beginning of last decade** in **the PGD community that allele drop out (ADO), which occurs when low DNA copy numbers are used as the starting material for genetic testing, is a challenging issue. Numerous papers have been published in order to reduce or eliminate this inherent risk. Some proposed to biopsy two cells from one embryo, others tested different lysis strategies; still others were trying to use whole genome amplification to obtain more DNA for replicate testing.** None of them appears to be fully effective. **Current understanding is that ADO is a very complicated matter and there may be many contributing factors. ADO varies from cell type to cell type. ADO is usually low in the healthy cells, such as lymphocytes and fibroblast cells harvested at the growth phase. Likewise in blastomeres, ADO may also vary according the healthy status of the cells/embryos. It is not unreasonable that a healthy diploid blastomere (D3, 7-9 cell stages) provide lowest chance of ADO.** Indeed, we have seen more aneuploidy/mosaicism in those slow developing or arrested embryos (4-5 cells on the morning of Day-3 post fertilization) in our FISH based aneuploidy tests.

Accumulated knowledge from the Human Genome Project facilitates the use of linkage markers which may reduce substantially the risk of ADO. Though it is highly desirable, markers are not always used even as of today for various reasons. **Finding informative linkage markers is not trivial task or an overnight procedure. Building whole sets of linkage markers for each disorder/mutation is a continuing process. In 2004, not all the laboratories were using linkage markers and not for every single mutation; in other words, multiplex PCR was not the standard in 2004.** During a period from 2001 to 2005, we successfully performed PGD for RB, an autosome dominant disorder with 50% risk without using markers. The reason *was* not that we were ignorant, but with the limitation that we had because we could not find markers that were informative for the couple. Three healthy singletons were born from 4 different IVF-PGD attempts. **I believe tests conducted by** Dr. Hughes **were proper, appropriate and within the standard of practice existing at the time for this couple.**

The tests performed on July 18-19, 2004 did **statistically** reduce **the risk, from 25% to a much lower percentage. It was proper to recommend the transfer of embryo #7 and 8 based upon both reports issued by** Dr. Hughes **and Genesis Genetics on** July 19, 2004. **Results in both of** Dr. Hughes' **reports prepared on July 19, 2004 were within the accepted level of risk and the level of risk agreed to by the patients.**

Another issue of embryological work using polar body biopsy is open for debate. Polar body biopsy or preconception genetic diagnosis was reported in 1990. However, the use of polar body biopsy has

been limited in a few laboratories around the world. A few laboratories that performing polar body biopsy, such as those in Germany and Italy, not because of its superior strategy but because of their country's law, As of today polar body biopsy for POD is yet to be a mainstream approach (see a most recent debate article by Geraedts et al. Human Reproduction, 2010, v25, pp575). It was not its technical difficult, but with its real benefits in routine PGD. If one looks ESHRE (European Society of Human Reproduction and Embrylogy) data collection from Ito IX (the latest one), one could only find few cases PGD using polar bodies as testing materials. At CRMI, we performed PB biopsy in the late 90's for balanced translocation; the girl is now over 12 year old, Nevertheless, we have not, as most of the labs in the world, used PB biopsy as a routine procedure.

Because of the ever-present risk of ADO, and other risk factors inherent in POD, CVS and amniocentesis are universally relied upon as a safety net in POD. CVS has been shown to be very accurate. I know from my experience that Dr. Hughes and Genesis Genetics will not take on PGD of a couple if they will not agree in advance to CVS or amniocentesis; and this is appropriate and within accepted standards.

From the documents I reviewed I believe that the couple was well informed on many occasions that there were risks of misdiagnosis and they have signed at least two important PGD consents, one from NYU, and one from Hughes' team. Dr Hughes went all the details, as much as he could, with the couple. Specifically, and without going into every detail in the consent forms, the Grossbaums demonstrated an understanding that this is not a perfect technology, it is complicated, **it is an experimental process**, lowering the risk to zero is not realistic or possible, **the technology can fail**, and follow-up confirmation testing (in the form of CVS or amniocentesis) is necessary. The Grossbaums agreed to go forward in light of the risks and alternatives, and they agreed with both NYU and Genesis Genetics to undergo confirmation testing in the form of CVS or amniocentesis.

Because of so many variables involved in PGD, the cause(s) of POD misdiagnosis is always difficult to pin down. Based on the literature most misdiagnosis is due to intercourse or unprotected sex. In a published data collection (ESHRE PGD consortium data collection VII: cycles from January to December 2004 with pregnancy follow-up to October 2005, Human Reproduction, 2008; Vol 23, No. 4, pp 741755), the best data collection and analysis in PGD community, the consortium stated on page 750 that "Eighteen misdiagnosis have been reported, 9 after POD for PCR and 9 after PGD or PGS using FISH. In all cases of misdiagnosis, unprotected sex during the POD cycle could be responsible as any embryos generated in vivo would not be tested." With this in mind, it is speculation to say that the bad result in this case was caused by the implantation of an affected embryo, as opposed to any of a number of other causes, including intercourse or unprotected sex by the Grossbaums.

In summary, I see a tragic case happened, **not because of any negligence, but unfortunately because of the complexity and the limitations of the PGD technology and likely other confounding factors.** Genesis Genetics did very professionally, and no deviations were seen from the standard of care.

Respectfully yours,

Kangpu Xu, Ph.D., HCLD.
Associate Professor
Director, Laboratory of Preimplantation Genetics
CRMI, Weill Cornell Medical College

EXHIBIT F

genetics institute

March 2, 2010

Stephen N. Leuchtman, P.C.
1380 E. Jefferson Ave.
Detroit, MI 48207

RE: Grossbaum v. Genesis Genetics & Hughes

Dear Mr. Leuchtman,

As this case has progressed, I have been provided with and have read the following materials:

1) **Medical Records of Genesis Genetics**
2) **Medical Records of IVF Center of New York University Medical Center**
3) **Reports from Dr. Garry R, Cutting and Dr. Charles M. Strom**
4) **Depostions of Mark R. Hughes, MD, PhD, Genesis Genetics; and Frederick Licciardi, MD, James Grifo, MD, PhD; Ms Alexis Adler, Kaycian Brown, R.N.; and Ms. Imelda Weill, New York University Medical Center**
5) **Depostions of Chaya Grossbaum (Volume 1 and 2) and Menachem M. Grossbaum.**

Both Chaya Grossbaum and Mechachem Grossbaum are carriers of a mutation for cystic fibrosis gene. They were referred to NYU IVF center and underwent IVF and biopsy at NYU and the specimens were sent and analyzed by Genesis Genetics. The child born from the procedure was found be affected with cystic fibrosis.

I spoke with the Grossbaums on March 25, 2004 and explained to them in detail what was going to happen in the course of preimplantation genetic diagnosis (PGD). I explained that the technology involved is imperfect and pushes medical diagnostic technology to its absolute limit, its practical limit and its theoretical limit. I explained that PGD technology **is in fact an experimental process**, and that **the technology can fail**. I explained that the risk of natural pregnancy was that there was one chance in four that the baby would be afflicted with cystic fibrosis, whereas that risk could be significantly lowered by PGD, but not eliminated. Each test for the cystic fibrosis mutation(s) is custom-designed, so it is extremely difficult to predict the chances of success in any given implantation following PGD. I advised people in 2004 that the risk of having an affected child is three to five percent, and I am certain I imparted this to the Grossbaums.

Further, Genesis Genetics and I will not perform PGD for a couple who does not agree in advance to

Genesis Genetics Institute, LIC
5555 Conner, Suite 1100
Detroit, Nit 98213
313-579-9650 313-544-4006 fax
GenesisGenetics.org

undergo chorionic villus sampling (CVS) or amniocentesis (amnio) early in the pregnancy. CVS is typically done at around ten weeks, and amnio is usually done at fifteen to sixteen weeks. I made the necessity of undergoing CVS or amnio known to the Grossbaums, and they agreed to this condition. At no time did they voice any objection or problem to me about CVS or amnia. Had they made any such objection, I would not have taken their case; and this fact was well known to NYU. I have had people over the years voice objections to amnio or CVS; and when this has happened, I have referred them to organizations who did not require conventional prenatal follow-up testing with amnio or CVS. It has always been an absolute, fully agreed upon, prior requirement of our program.

After the Grossbaums were informed about information including all of the above and more, they advised that they had no questions and were satisfied with what was going to be done. In may, 2004, I sent them a Preimplantation Genetic Diagnosis Patient Informed Consent, which the Grossbaums signed on June 4, 2004 and I countersigned on July 16, 2004. this Informed Consent included the following language, to which the Grossbaums agreed: "between ten and fifteen weeks of pregnancy you will undergo conventional prenatal genetic testing in the form of chorionic villus sampling (CVS) or amniocentesis. The sample will be used to confirm the predicted PGD test results." Based upon this written agreement following the oral agreement on March 25, 2004, I went ahead with PGD for this couple. My review of the NYU records and the depositions of the NYU people confirms that at no time did the Grossbaums ever voice any reservations to NYU about undergoing CVS or amnio.

As Dr. Kangpu Xu has pointed out in his report, **an open question and a central issue in** PGD **is that PGD has its limitations because it is a single cell based test. It has been recognized** since **the beginning of last decade in the PGD community that allele drop out (ADO), which occurs when low DNA copy numbers are used as the starting material for genetic testing, is a challenging issue. Numerous papers have been published in order to reduce or eliminate this inherent risk. Some proposed to biopsy two cells from one embryo, others tested different lysis strategies, still others were trying to use whole genome amplification to obtain more DNA for replicate testing. Current understanding is that ADO is a very complicated matter and there are may be many contributing factors. ADO varies from cell type to cell type. ADO is usually low in the healthy cells, such as lymphocytes and fibrolast cells harvested at the growth phase. Likewise in blastomeres, ADO may also vary according the healthy status of the cells/embryos. It is not unreasonable that a healthy diploid blastomere (D3, 7-9 cell stages) provide lowest chance of ADO.**

The use of linkage markers in 2004 for cystic fibrosis mutations was not standard of care in the field of PGD. Multiplex testing was done at the time in some laboratories for some diseases, but it was very new and experimental in early 2004, including when the Grossbaums underwent PGD and IVF. Even today for various reasons, these procedures are not in universal use. **Finding informative linkage markers is not trivial task or an overnight procedure.** As Dr. Kangpu Xu has pointed out, **building whole sets of linkage markers for each disorder/mutation is a continuing process. In 2004, not all the laboratories were using linkage markers and not for every single mutation; in other words, multiplex PCR was not the standard in 2004. I believe the tests conducted by** my lab and myself **were proper, appropriate and within the standard of practice existing at the time for this couple.**

The tests performed on July 18-19, 2004 statistically reduced **the risk, from 25% to much a much lower percentage. It was proper to recommend the transfer of embryo #7 and 8 based upon both**

reports issued by myself **and Genesis Genetics.** I prepared two reports on July 19. One was somewhat abbreviated; and the other went into greater detail. The **results in both of** my **reports prepared on July 19, 2004 were within the accepted level of risk and the level of risk agreed to by the patients.**

When 1 biopsy cells, I can comment to a degree on the likelihood that they will be affected or carriers of the disease we are looking for; but I cannot comment on the condition of the embryos on the day of implantation. Ultimately, the decision to go forward is that of the couple involved based on the best information their doctor and my lab and I can impart to them as of the day of implantation or transfer.

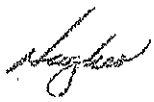
Dr. Kangpu Xu addresses polar body biopsy at great length in his expert report. I agree with his conclusions.

As allluded to above, **because of the ever-present risk of ADO, and other risk factors inherent in PGD, CVS and amniocentesis are universally relied upon as a safety net in PGD.** It was within the applicable standard of care for my lab and myself to insist upon agreement to CVS or amniocentesis as a condition to doing PGD. The Grossbaums agreed to go forward in light of the risks and alternatives, and they agreed with both NYU and Genesis Genetics to undergo confirmation testing in the form of CVS or amniocentesis.

As was pointed out by Dr. Kangpu Xu, **because of so many variables involved in PGD, the causes of PGD misdiagnosis** are **always difficult to pin down. Based on the literature most misdiagnoses** are **due to intercourse or unprotected sex. In a published data collection (ESHRE PGD consortium data collection VII: cycles from January to December 2004 with pregnancy follow-up to October 2005, Human Reproduction, 2008; Vol 23, No. 4, pp 741755), the best data collection and analysis in PGD community, the consortium stated on page 750 that "Eighteen misdiagnosis have been reported, 9 after PGD for PCR and 9 after PGD or PGS using FISH. In all cases of misdiagnosis, unprotected sex during the PGD cycle could be responsible as any embryos generated in vivo would not be tested." With this in mind, it is speculation to say that the bad result in this case was caused by the implantation of an affected embryo, as opposed to any of a number of other causes, including intercourse or unprotected sex by the Grossbaums.**

In summary, I believe that the unfortunate result in this case occurred, **not because of any negligence, but unfortunately because of the complexity and the limitations of the PGD technology and likely other confounding factors.** We acted professionally and at all times consistently with the standard of care as it existed at the time.

Very truly yours,



Mark R. Hughes

EXHIBIT G

UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY
DOCKET NO. 07-cv-1359

CHAYA GROSSBAUM and MENACHEM GROSSBAUM, her spouse, individually, as guardians ad litem of the infant, ROSIE GROSSBAUM,

Plaintiffs,

v.

GENESIS GENETICS INSTITUTE, LLC, of the State of Michigan, MARK R. HUGHES, MD, NEW YORK UNIVERSITY SCHOOL OF MEDICINE and NEW YORK UNIVERSITY HOSPITALS CENTER, both corporations in the State of New York, ABC CORPORATIONS 1-10 and JOHN DOE 1-10,

Defendants.

DEPOSITION OF:
DR. KANGPU XU

T R A N S C R I P T of testimony taken stenographically by and before PHILIP A. FISHMAN, a Certified Shorthand Reporter and Notary Public of the State of New Jersey, at the offices of LOWENSTEIN, SANDLER, ESQS., 1251 Avenue of the Americas, New York, New York on Thursday, May 13, 2010, commencing at three o'clock in the afternoon.

PHILIP A. FISHMAN
COURT REPORTING AGENCY
89 Headquarters Plaza North
Morristown, New Jersey 07960
973-285-5331 - FAX 732-605-9391

INDEX

EXHIBITS

APPEARANCES

NUSBAUM, STEIN, GOLDSTEIN, BRONSTEIN & KRON, ESQS.
20 Commerce Boulevard
Succasunna, New Jersey
BY: LEWIS STEIN, ESQ.
Appearing on behalf of the Plaintiff.

STEPHEN N. LEUCHTMAN, PC
1380 East Jefferson Avenue
Detroit, Michigan
Appearing on behalf of Genesis Genetics Institute and Dr. Hughes

MARSHALL, DENNEHEY, WARNER, COLEMAN & GOGGIN, ESQS.
425 Eagle Rock Avenue
Roseland, New Jersey

BY: JAMELE A. HAMAD, ESQ.
Appearing on behalf of New York University School of Medicine and New York University Hospitals Center.

KANGPU X U,

1300 York Avenue, New York, New York, having been duly sworn according to law, testifies under oath as follows:

DIRECT-EXAMINATION BY MR. STEIN:

Q. Good morning, Dr. Xu.

A. Good morning.

Q. Am I pronouncing your name correctly?

A. Very accurately.

Q. We are here today to take your deposition, which is merely a multi syllable word to describe a question and answer session in which I am going to ask you some questions and your answers and my questions are going to be recorded by the gentleman who sits to my left and your right, who is a Certified Shorthand Reporter.

At the end a booklet, a transcript of your answers and my questions will be prepared for use in this litigation.

To that end, I would like to give you a couple of instructions.

A. Okay.

Q. One, it is not unlikely during this question and answer session that I will ask you a question that makes no sense to a specialist in genetics, since I am, needless to say, not trained in that specialty, so if I

5

should pose a question that makes no sense to you, please indicate that to me and I will be happy to withdraw the question and try and rephrase it or give you an entirely new question.

Do you understand that?

A. Yes.

Q. Because if you do answer my question both I and counsel assembled here have a right to assume that you understand my question.

Do you understand that?

A. Yes.

Q. A few other instructions.

There is likely to come a time when the meaning of my question will become apparent to you before I finish speaking it?

Please do your best to refrain from speaking until I conclude my question so that the reporter does not have to take both of us speaking at once.

Along the same lines please answer all of my questions verbally so that the reporter doesn't have to interpret those common elements of speech in which you either gesture or give the classic "uh-huh" to an answer, so please try to answer all my questions verbally.

A. Okay.

6

Q. Also I should tell you that since this deposition may be used in the course of litigation, even though you are sitting here in a law office, you should treat the question and answer session with the same seriousness as if you were giving testimony in open court.

Do you understand that?

A. Yes.

Q. And that is the reason that you have been placed under oath here today.

Do you understand the significance of the oath and the consequences for you to violate that oath by testifying untruthfully?

Do you understand that?

A. Yes.

Q. Okay. And with that I would like to ask you have you had this experience before? Have you ever had your deposition taken prior to today?

A. No.

Q. In coming to this deposition today, could you tell me whether you read any documents in preparation for this deposition?

A. Yes. I read the documents Mr. Leuchtman provided to me. I think I listed these documents in my report.

Q. Okay. And by your "report" you are referring to a letter dated February 26, 2010. Is that correct?

7

A. Yes.

MR. LEUCHTMAN: I should say since the report we have sent --

MR. STEIN: Mr. Leuchtman --

MR. LEUCHTMAN: The doctor -- there are two other deposition transcripts.

MR. STEIN: I didn't ask him anything about what he got since his report, so if I am interested in that in my deposition I will ask him.

Okay?

Thank you.

Q. Now, you referenced the documents that you reviewed, you said, were in your report, is that correct, before you wrote the report?

A. Yes.

Q. Okay. Now, did you review any other documents than those listed as items No. 1, 2, 3 and 4 in your letter of February 26, 2010?

A. What do you mean, the "reports"?

I read or referenced all published articles.

Q. Now, in preparation for today's deposition, did you reread any of those documents that you listed as items 1, 2, 3 and 4 in your report?

A. I came back a couple of these, yes.

Q. I am sorry?

8

A. I came back to some of the documents, yes.

Q. Okay. And did you review anything else besides what is listed and mentioned in your letter of February 26, 2010?

A. Well, in the reports I mention these, what is it, ESHRE, European Society of Human Reproduction and Fertility published papers, I think mainly I reviewed.

Q. Since you sent your letter of February 26, 2010, did you review anything else concerning this case besides what you have mentioned in your report either in the list at the beginning of the report items 1 to 5 or literature that you refer to in the content and body of your report?

A. I reviewed the two depositions sent to me from Mr. Leuchtman by Dr. Cutting and Dr. Strom.

Q. Okay. And do you know Dr. Cutting?

A. I met him once, I believe.

Q. Okay. And do you remember where that was?

A. I think it's in 2002 in Johns-Hopkins.

Q. What were you doing there?

A. I was invited by IVF clinic to give a lecture for preimplantation genetic diagnosis.

Q. And --

A. And the director there, I think, showed me, introduced me to his lab very briefly, I believe I met

him.
Q. Now, when that lecture that you gave at Johns-Hopkins in 2002 did you prepare a paper in connection with that lecture?
A. No.
Q. Okay. Did you provide anything in writing to the attendees at that lecture?
A. No. I don't think so.
Q. When you said you don't think so, are you unsure?
A. Yes. I am sure.
Q. I am sorry?
A. Yes. I am sure. I did not provide any written material.
Q. Okay. You know Dr. Charles Strom?
A. Also from professional meetings, yes.
Q. And when you say "from professional meetings," are you referring to more than one occasion that you know Dr. Strom?
A. I remember definitely once in late '90s I went to Chicago, there was a preimplantation genetic diagnosis meeting actually held in RGI, so I was there.
Q. All right.
A. He was there.
Q. Do you remember when that was specifically?
A. It's late '90s.

I don't remember the specific year.
Q. And do you know Charles Strom as one of the most renowned pioneers in preimplantation genetic diagnosis?
A. Yes.
Q. Do you have a present recollection of reading his deposition and what he says in his deposition?
A. I do have a few -- yes, a few -- a few points that he has made.
Q. Did you take any notes when you read his deposition?
A. No.
Q. Okay. And did you have a present recollection of anything that he said in his deposition that you read that you disagree with?
A. Yes.
Q. Specifically what do you recall you disagreed with?
A. One of the disagreements, I think, is polar body biopsy.
Q. And what did you disagree with his comment about "polar body biopsy"?
A. He believed that it is a common practice and actually polar body biopsy is not as standard of a procedure in many PDG labs.
Q. Is it done in any PDG labs?

A. In a few PDG labs.
Q. And which ones do polar body analysis?
A. Well, the pioneering lab is from Chicago, RGI, Drs. Verlinsky and Strom are the pioneers of that technology or that technique, but it has not been widely used.
Q. Was it used anywhere else besides Chicago?
MR. LEUCHTMAN: May I ask for clarification. We are talking about within the United States?
MR. STEIN: I didn't talk about limit it to anything. My question was is it used anywhere else besides RGI.
MR. LEUCHTMAN: In that case I will object.
MR. STEIN: Okay. You got your objection.
A. We used in my lab. I used it in late '90s until this year, but occasionally for specific reasons.
Q. And for what reason?
A. Well, for example, this year we used one for a patient who has a de novo mutation of retinoblastoma, that's what we are after, preimplantation case. De novo meaning the mutation occurs from her, not inherited from her parents, so we could not establish a linkage, so we did a polar body biopsy, try to see the linkage marker

and the mutation, so we use that for that case.
We started to use in late '90s for female balance translocation and, actually, the first baby that, a live baby from balance translocation was born in late '90s, so we have been using that technique, but not as a routine.
Q. Okay.
A. And, I think, in Germany or, perhaps, Italy, they are also using polar body biopsy because the law prevents them to do Day 3 embryo biopsy and from the literature I read the one published by a consortium from European Society of Human Reproduction, the data shows, that's the best data, I think, collected in PDG area because they have very good organizations.
I think the data in mid 2000 or let's say from beginning of 2000 and collected eight years, the percentage of cycles use polar body biopsy is about seven percent, so I don't think it's widely used and the last year the data shows slightly increase from seven percent to about 15 percent. I think I have the paper there, so I think from that world consortium collection it's 15, 16 percent, that's polar body biopsy.
Considering Germany and Italy, those are the places where law prohibit use Day 3 biopsy, so that's what my opinion or my understanding is how wide you use

13

or how less frequently used as polar body biopsy.
Q. Okay. Do I understand then that you used polar body technique in the particular case that you described for us in your de novo mutation, because you were not satisfied that you could get the linkage analysis for that patient. Is that correct?
A. Yes.
Q. Do you do single cell biopsies on embryos for that patient?
A. Yes.
Q. And, I take it, that you were not satisfied that single cell biopsy would give you enough data to protect you against misdiagnosis without doing polar bodies in addition. Is that correct?
A. This main purpose establish linkage, because we had markers, not particularly for -- for the diagnosis. We purposely for establishing the linkage.
Actually, for that case of 20 embryos we only did a 10 polar body biopsy or biopsies, polar body biopsies from 10 oocytes. The remaining embryo we didn't do for technical reasons -- you know -- if you want me to go through that and give you further details.
Q. Why did you want to do more than a single cell biopsy for that patient?
A. I am sorry.

14

Q. Why did you want to do more than a single cell biopsy of the embryos for that patient?
A. As I said, because we could not establish a linkage, so polar body will give you linkage after that mutation and as blastomere markers. We could have her parents, but that would not be informative, because of a de novo mutation.
Q. But why did you want to do linkage in addition to doing single cell blastomere studies of the embryo?
A. Linkage does increase the accuracy.
Q. Now, I would like to direct your attention to your CV for a moment.
By the way, did you bring a copy of your CV with you?
A. Yes, I have it.
Q. Okay. Now, your CV states that you had the position of associate professor at the Center of Reproductive Medicine and Fertility at the Weill Medical College at Cornell?
A. Yes.
Q. What are your duties in respect to that position?
A. I am director of the laboratory of preimplantation genetics, so I have clinical duties which involve clinical preimplantation genetics diagnosis. Specifically I do biopsy and I direct,

15

supervising the lab, my staff, arranging from three to sometimes five, because I have a visiting scientist and I do biopsy and we also provide clinical services for preimplantation genetic diagnosis and we are doing what we call cytogenetics or FISH based PGD and also we provide services for PCR based, which is a single gene disorders, including cystic fibrosis, Sickle Cell anemia, retinoblastoma, and so on. We have provided a dozen disorders that we do.
Q. So other than your responsibilities in terms of being director of a clinical laboratory as you have described it, do you have any teaching responsibilities?
A. Limited.
I do sometimes give lectures to the medical students and I have interactions with fellows. We have a reproductive fellows we call "RE fellows" and we have interactions with the fellows helping them to do research project.
Q. Okay. And how often do you lecture the medical students?
A. About once a year, not very often.
Q. Okay. And how often do you -- withdraw that.
Do you actually lecture the fellows in the reproductive genetics fellowships?
A. Mostly is personal interaction one-on-one, but,

16

yes, sometimes if they request, I will do the lecture, yes.
Q. Do they work in your clinical practice along with you and learn from you, is that the right procedure?
A. They are mainly IVF, doing IVF, but PGD is a small part of IVF, so they learn PDG part as well.
Q. How long have you been doing the PDG studies for cystic fibrosis similar to autosome diseases?
A. Well, to start with when I recruited in 1992, actually, when I started at that point, we published a paper in human reproduction in 1993 and we tried to amplify single cell and then detect cystic fibrosis, one of the mutation delta F508.
Q. That was research?
A. That was research, yes.
Q. Research.
When did you offer clinical services to the public, when did you start doing that?
A. In late '90s.
Q. When you say "late '90s," you are talking about 1998?
A. About.
I don't remember the specific year.
Q. And at that time you were not only in a clinic that retrieved the embryos, created the embryos and also

17

did the genetic studies of the embryos to determine whether the embryos were fit for reimplantation?

A. Yes.

Q. And but you were there for about six years before that, you were at Weill Cornell from 1992, I believe, you indicated?

A. Yes.

Q. They had a fertility clinic between 1992 and 1998?

A. Yes.

Q. Okay. Did you at that time collaborate with any laboratories to do PGD studies?

A. We are doing in-house actually. Well, collaborated, I don't know what specifically collaborate means. Research collaboration.

Q. I will rephrase the question.

A. Okay.

Q. The process by which PDG studies are done involves individual fertilization procedures and it also involves an analysis of the cells of embryos to determine the suitability for implantation. Correct?

A. Yes.

Q. Okay. Now, I think you indicated -- I understand starting about 1998 your clinic began to do in-house, so to speak, the complete process. Not only did you do all

18

aspects of the invitro fertilization in the hospital but also you analyze the embryos to determine whether or not the embryos were appropriate for implantation in connection with the mutation that you were working with. That's the process. Correct?

A. That's the process.

Actually, our clinic started offering PDG clinically from 1992. That's our center.

The first PGD baby in US was born from our center.

Q. Okay. Now, who did the analysis of the embryos in connection with that PDG workup?

A. From our center?

Q. Yes.

A. Dr. Grifo was there, Jimmy Grifo. Dr. Santiago Munne was there, so that period of time, and they left mid '90s.

Q. Grifo went to NYU and Munne went to Saint Barnabas in New Jersey?

A. Right.

Q. Now, your laboratory was not equipped, according to what I understand, to do the assessment of the blastomeres to determine the suitability for implantation genetically until sometime in '90, '98, so which laboratories did you use to do that analysis?

19

A. That is not -- I think it's not correct.

We -- our lab was equipped, so we continued from 1992. We did not stop.

When these people, Dr. Grifo and Munne left I took over. I was the head of the PGD program.

In other words, because -- I am sorry -- during that period of time PGD is more regarded as a research, so I took over the research group and we continued.

We had a microscope, we had a PCR machine. We have a genetic analyzer. We had a good one.

Q. Did you receive embryos from any other fertility clinics during that period of time for analysis?

A. No.

Q. Are you receiving them at this time?

A. No.

Q. So your laboratory is not available to outside clinics, fertility clinics to do PGD studies. Is that correct?

A. Correct. Correct.

Q. Now, in this case you're acting as an expert witness on behalf of Genesis Genetics and Dr. Hughes.

Do you understand that?

A. Yes.

Q. Have you ever acted as an expert in any other case?

20

A. No.

Q. Who is the chairman of your department?

A. Dr. Zev Rosenwaks.

Q. Does he know about your activities in offering an expert opinion in this case?

A. I mention it to him.

Q. When did you do that?

A. I think -- I think the day Mr. Leuchtman asked me, I think.

Q. Okay. How did you get involved in this case?

A. Mr. Leuchtman approached me.

Q. Okay. Was he the first person to approach you?

A. Yes.

Q. Did you have any contact with Dr. Hughes at about the time that Dr. Leuchtman approached you?

A. No.

MR. HAMAD: We aren't doctors.

Q. Have you talked to Dr. Hughes about this case?

A. No.

Q. Have you communicated with Dr. Hughes by e-mail about this case?

A. No.

Q. Has Dr. Hughes communicated with you by e-mail about this case?

A. No.

Q. Has -- have you ever been sued in any capacity while you were at Cornell?
A. **No.**
Q. Were you ever sued in your -- when you practiced as a veterinarian to the extent that you did?
A. **No.**
Q. Has anyone, to your knowledge, at Cornell been sued regarding the services that they render in either invitro fertilization or PGD?
A. **Not that I know of, no.**
Q. Now, obviously, you know Dr. Grifo since you were colleagues at one time?
A. **Yes.**
Q. And do you still see Dr. Grifo from time to time?
A. **I haven't seen him for years.**
Q. Years?
A. **Right.**
Q. Okay. And when you say "years," give me an estimate of the years.
A. **Probably two, three.**
We did meet by passing in professional meetings, but I don't remember I saw him last year. I am sure -- not I am sure -- probably he went, but I didn't.
Q. Where was it last year?
A. **It's in Atlanta.**

Q. Do you know Dr. Licciardi?
A. **I don't think I know him personally.**
I saw him at the meetings. I know who he is, but I never kind of met him formally.
Q. And do you know anybody else on the NYU staff in their fertility clinic?
A. **I know Alex -- Alexis Adler. She worked in Cornell before.**
Q. In what capacity does she work at Cornell?
A. **She was an embryologist.**
Q. Okay. Anybody else at NYU that you know?
A. **I don't know exactly who is there, but maybe one or two fellows from our center were there, if they are still there.**
I think I may know them.
Oh, Dr. Noyes, Nicole Noyes, I think I know her, because she worked also before at Cornell.
Q. Now, I take it you agreed to be an expert when Mr. Leuchtman called you. Is that correct?
A. **Yes.**
Q. Can you tell me what documents -- what formed the transmission of documents? How did you get them?
A. **He FedEx to me.**
Q. And you created a file with the records that he sent you?

A. **I don't have a file. I have the package.**
Q. Do you have the package here?
A. **Yes, I have it here.**
Q. May I see it, please.
A. **Sure.**
MR. LEUCHTMAN: It's somewhat thicker, unlike others we send with all the depositions.
MR. HAMAD: You got to start early this morning.
MR. STEIN: First I am going to tell you point blank, that -- I consider that to be an inappropriate comment during the course of a deposition of a witness and if that type of thing continues, I am going to ask that we get appropriate recognition by the court, please.
MR. HAMAD: You are talking --
MR. STEIN: You haven't said a word.
MR. HAMAD: I am just making sure.
Q. Among the materials that you were showing me I see, are the grafts from the studies done at Genesis Genetics?
A. **Yes.**
Q. And I take note that they are color coded. There are some red lines and there are some, what appear to be, black lines. Is that correct?

A. **Right.**
Q. Was it significant to your evaluation of these grafts that they be color coded?
A. **Yes.**
Q. I see also that there are some stickers on two pages what I would describe as a purple color.
Did you put those on there?
A. **Yes.**
Q. Now, in looking at what constitutes your packet of documents that you reviewed in this case, I do not see any letters of transmission or transmittal to you.
Do you have any records or documents to show when those records were transmitted to you?
A. **I don't have it.**
Q. Can you tell me when you got those records?
A. **Was it in February? In February it must be.**
Q. Okay. Now, you say "February it must be," I take it, because you are looking at your report?
A. **The report.**
Q. And you assume you got those records before you wrote your report and so, therefore, it was sometime in February, you believe, you got those records.
A. **Right, except Strom and Cutting's depositions, obviously.**
A. **Yes.**

Q. They were taken after you wrote your report. Correct?
A. **Right.**
Q. Now, I notice in your letter -- and whenever I refer to a "letter," I am not going to spell it out each time -- we always are referring to the February 26, 2010 letter, I take it.
Do you understand that, Doctor?
A. **Yes.**
Q. Okay. In your letter you indicate and I quote, "We have completed over 1300 cases of PGD for a variety of indications including more than 70 cases for cystic fibrosis covering more than a dozen" and then it says "of CF mutations."
Can you tell us in those 70 cases --
A. **Uh-huh.**
Q. -- did you actually look at some statistics before including that information in your report?
A. **What do you mean statistics?**
Q. Is this a statistic that is taken off the top of your head or is there a compilation of the 70 cases which you can look at a statistical record and know that there were 70 cases? How did you determine that number?
A. **We have the record.**
Q. Okay.

A. **Our lab.**
Q. And can you tell me how many of those cases of cystic fibrosis mutations involved compound heterozygous parents?
A. **That I don't remember. I have to check. No, I don't have that number.**
Q. Can you give me any estimate?
A. **I can only estimate definitely less than 50, 50 percent.**
Q. Okay.
A. **That, I think, as far as I could estimate.**
Q. And what are compound heterozygous mutations?
A. **I am sorry.**
Q. What are compound -- can you explain what "compound heterozygous" mutations are?
A. **Compound heterozygous mutations, the couple or husband or wife, we call the partners, because of the marriage, one partner carries one mutation is different from the other partner's mutation. It's a compound. In other occasions they may carry the same mutation, delta fibroid and cystic fibrosis is most common.**
Q. But if the partners carry the same mutation, that's called something other than compound heterozygous?
A. **That's correct.**

Q. What is that called?
A. **Called the same mutation.**
Q. Is that called homozygous?
A. **Homozygous is the meaning, it's the same, the same mutation. It's a homozygous -- you don't refer a couple as a homozygous. Homozygous refers to individual.**
Q. Okay. Have you ever had a misdiagnosis in doing molecular testing at Cornell?
A. **Not that I know.**
Q. And from what you already said I understand you to do linkage analysis. Is that correct?
A. **We started to do -- try to do linkage analysis in early 2000. Actually, we had a case for retinoblastoma and this is autosome dominant disease. We try to develop that linkage marker and we had three and unfortunately for that particular case, it was not informative, so the patient, we discussed it with the patient. The patient decided to go ahead. They said if you could give us from 50 percent of a chance affected down to allele drop out, five, ten percent, they say that's significantly reduce the risk, so they wanted to go ahead. So we went ahead and, well, they had a healthy baby, and the first one I actually attempt wasn't successful. The second one they had a healthy**

girl. A year later they come again and had a healthy boy and another year and a half, maybe, they got a third healthy baby, so that was very lucky family. They are so grateful, but in that case we couldn't find -- you know -- in the time frame we couldn't offer linkage marker.
Q. Is that the case that you mention you reported on?
A. **Yes.**
Q. In the literature, the one you just described?
A. **Yes, we published that.**
Q. Now, is it your testimony that it is that case it's the first time you used linkage analysis?
A. **I think it is, but I am not really sure.**
Q. Okay. And about what year was that, Doctor?
A. **It was -- well, it started in the beginning of 2000 around. I can't be 100 percent --- I can't be 100 percent sure.**
Q. Is it your testimony that no linkage analysis was done at your laboratory for cystic fibrosis prior to 2000?
A. **I can't be sure but it's likely.**
Q. Okay. Is it your testimony under oath that no cystic fibrosis analysis was done using linkage procedures in cystic fibrosis prior to 2004?

A. In my lab?
Q. Yes.
A. That will be true. That will be correct. Yes.
Q. Okay. When is the first occasion that you used linkage analysis for a cystic fibrosis mutation?
A. Mid 2000. Mid 2000, I would say.
Q. When you say "mid 2000," what year are you referring to?
A. I don't remember exactly what year unless I go back to look at our lab records.
Q. Okay. Is it possible that you were doing linkage analysis in 2004?
MR. LEUCHTMAN: Prior to 2004?
Q. Yes.
A. If retinoblastoma is one that we were looking, yes.
Q. Okay. And is it possible that you were doing linkage analysis for cystic fibrosis in early 2004?
MR. LEUCHTMAN: I object to the form of the question.
It's speculation.
A. I don't remember if we did.
Q. Okay. Are you able to say definitely that you did not do linkage analysis for cystic fibrosis in the year 2003?

A. No, I can't say definite.
Q. Do you routinely do linkage analysis for cystic fibrosis mutations currently in the year 2010?
A. Yes.
Q. And have you been doing it currently for several years now in cystic fibrosis?
A. Several years, I would say, yes.
Q. Okay. Have you ever been approached by other fertility centers to do PGD analysis for them?
A. Yes.
Q. And you have declined?
A. Well, that's our center's policy. We decided not to take outside specimens.
Q. Now, in connection with the operation of your clinic, do you yourself actually participant in the IVF process in either overseeing or participating in removing the eggs?
MR. HAMAD: I object to the form.
A. Yes, I do biopsy.
Q. And after the biopsy is completed and the PGD study is done, do you counsel with the parents about the use of the embryos?
A. No, I don't. I don't directly consult with the parents.
Q. Do you meet with the parents at any time --

A. No.
Q. -- during this process?
A. No.
Q. And who does that in your lab?
A. Not the lab.
Our center the physicians, the nurses and the genetic counselors and they usually have a geneticist at Cornell or outside.
These are the people they will meet.
Q. All right.
Do you decide whether the PGD results are -- create embryos and that are recommended to the family to be used?
A. What --
MR. HAMAD: Objection to form.
You can answer.
A. We produce the report and I sign the report and on the report we will recommend which one transfer or not transfer. Then the report goes to the embryology lab, and the embryology lab, physician, patient, those are the ones to decide which one to transfer.
Q. Did you do follow-up to see the results of the IVF -- do you do follow-up to determine the results of IVF either with respect to the prenatal studies or the delivery of a live baby?

A. Our center work as a team. We have the nurses, we have genetic counselors and they do the follow-ups.
Q. Thank you.
And that's the policy of your center. Is that correct?
A. That's the way we operate, yes.
Q. And do you participate in establishing those policies and practices?
A. Yes.
Q. Okay. And why do you do follow-up for what purpose?
A. Well, it's a quality assurance purposes. We try to improve constantly our services.
That's the main purpose.
Q. Now, are you familiar with the consent forms that the partners are required to sign when they undertake PGD testing?
A. Yes.
Q. And do those consent -- do you have any copies of those consent forms here?
A. I don't have our center's consent, no.
Q. Are you familiar with the consent form?
A. Well, I don't remember all the details. Yes, I know what is the main part.
Q. Okay. And is it a condition for you to provide

PGD studies that the parents of the hopeful child, agree to do prenatal testing by either CVS or amnio?

A. Yes.

Q. And if the parents don't consent, do you refuse to do the PGD analysis?

A. Well, I don't know that part whether they refuse to do it, because my lab get is already consented.

Q. Right.

A. The consenting process is by the physicians and now by the genetic counselors.

Q. Okay.

A. So I only perform the patient that already consented.

Q. Okay. And, I take it, it's not your role to understand anything about the family's attitude toward abortion. Is that correct?

A. That's correct.

Q. I take it English is a second language for you?

A. Yes.

Q. And you came to Canada sometime around 1987, from China?

A. From Denmark.

Q. From Denmark. You studied in Denmark?

A. Right. I obtained by PhD in Denmark.

Q. And China is -- Chinese is your native language?

A. Yes.

Q. And how old were you when you left China?

A. I must be 31.

Q. And did you return at all after you got your PhD in Denmark for any extensive length of time?

A. No. Only a short visit.

Q. Now, the report that you have provided, did you have any assistance in preparing this report?

A. No. I think I discussed a few points with Mr. Leuchtman, but not -- I wrote my report.

Q. Okay. And did you talk to Dr. Hughes about the content of your report?

A. No.

Q. Have you ever discussed this case with Dr. Hughes?

A. No.

MR. LEUCHTMAN: You asked that, but ask it again if you want.

Q. Have you seen Dr. Hughes' report in this case?

A. Dr. Hughes' report, yes, I did.

Q. Okay. And do you recall the circumstances under which you got Dr. Hughes' report?

A. I am sorry.

Can you repeat?

Q. The circumstances under which you got Dr. Hughes' report, how did you get it?

A. The report is included in this package.

Q. Dr. Hughes has issued an opinion letter dated March 2, 2010.

Have you seen it?

A. Opinion letter?

MR. STEIN: Suppose, Phil, at this point we mark for identification first Dr. Hughes' report.

MR. LEUCHTMAN: If that was included in the package, then, yes.

If not, then it's post this stuff.

Q. Do you have your report, Doctor?

A. Right here.

MR. STEIN: Suppose we mark this P-1 for identification.

(Report is marked as Exhibit P-1-Xu for identification.)

MR. STEIN: Do you have a clean copy, Mr. Leuchtman, of Dr. Hughes' report?

MR. LEUCHTMAN: I think I might.

Yes, it's attached somewhere.

The short answer is yes.

MR. STEIN: Can we mark that and we can show it to Dr. Xu.

MR. LEUCHTMAN: Yeah.

(Genesis Genetics Institute report is marked as Exhibit P-2-Xu for identification.)

MR. STEIN: We are back on the record.

Q. Now, we have marked P-1-Xu for identification and that's your report, so I will return it to you because I have a copy and I will ask you this: How was this report produced?

Did you type it?

A. Yes, I did.

Q. And explain to me, what was the mechanics, how did you create this letter that we have, the three-page letter dated February 26, 2010?

A. Well, I read the package and then form an opinion and then I put a few points that I think I wanted to express my opinion, then I typed in my computer and I printed.

Q. Okay. Did you make any notes from the records that you read to use in typing this on your computer, this report?

A. I am sorry.

Q. Did you make any handwritten notes?

A. No, I worked along with the computer.

Q. Okay. So do I understand that there were no handwritten notes that you made as you went through the records to formulate the opinions that you ultimately

put on paper, on your computer, and then printed on this letter of February 26th. Is that correct?

A. I made -- I might make the notes. These are the notes. I would not keep them just when I finish the report.

Q. Okay. When you finished your report, was that -- was that the date that's on there, February 26, 2010, when you finished this report?

A. Yes.

Q. Did you send it to anybody for approval before you sent it to Mr. Leuchtman?

A. No.

Q. Did you show it to the chairman of your department before you sent it to Mr. Leuchtman?

A. No. I only mention that to him and he said this is your own decision and that's after mention that and never touch this anymore.

Q. Were you paid for the services in putting together this report?

A. No, not --

Q. Did you send a bill?

A. No, I have not.

Q. And are you going to send a bill?

A. That I don't know. I think it's -- I haven't even thought about it.

Q. Are you doing this as a favor to Dr. Hughes?

A. I don't think it's a favor, just I was asked and I have my own opinions in the PGD area we do see misdiagnosis and what causes it. It's not that easy to determine. I think I wanted to express my opinion.

Q. And so it was because of your interest in expressing your opinions that you got involved in this case. Is that correct?

Is that what you are testifying to here today?

A. I wouldn't say exactly, but part of it, yes.

Q. Now, you are here today to give your deposition.

Do you have an arrangement to be paid for your time here today?

A. I am sorry.

Q. Do you have an arrangement to be paid for the time that you are here today giving your deposition?

A. No.

Q. Do you expect to be paid for being here today?

A. That I don't know. I don't have expectations, but if that is a practice, I will take it, but I have not sent a bill or anything, or discussed anything of a payment.

Q. Okay. And have you thought about what kind of fee you were -- you would charge for coming here today?

A. No, I have not thought about it.

Q. Now, was it -- withdraw that.

When you provided this letter to Mr. Leuchtman -- it's addressed to him -- dated February 26, 2010, did you give him a disc with it?

A. No.

Q. So you just gave him the three-page letter. Is that correct?

A. Right.

Q. And it was your decision to line up the records that you saw one, two, three, four and five. Is that correct?

A. Well, that part, I think, I talked to Mr. Leuchtman and he said if you read it would be a good idea to list it.

Q. Okay. And so then you listed it?

A. Yes.

Q. And it was your writing that listed it, one, two, three, four and five?

A. Right.

Q. And as we look at the large paragraph that is at the bottom of Page 1 of your report that begins, "As you probably know" --

A. Uh-huh.

Q. If you --

A. Yes.

Q. If you look at that paragraph I see in the second line you write and I quote, "I have published a number of papers in PGD."

Now, did you omit putting an "A" between "published" and "numbers" or is it just your style of writing to say you have "published number of papers?"

A. I think that's the one that I am not native English. It's not a style. I think --

Q. Okay. And is that true in the next line when you say "We studied a new procedure call Primer Extension Preamplification."

That's also your manner of using English?

A. Not -- I wouldn't say "manner." If -- when I publish things I will have my secretary or helper to send. For this particular document I did not ask for -- I thought I have to keep as a confidential, so I did not ask anybody to editor.

I did go through the spelling check, but I notice still there is spelling mistakes, but it's -- you know -- I think my own product, these are mistakes from my own.

Q. Okay. And I also notice as I go further in that paragraph, that I read the sentence down, you see where it says, "Further, I am a certified laboratory directory."

41

Are you a directory or a director?
A. It's so embarrassing, a director.
Q. Okay. And I was looking to see whether there was a verb in that sentence. Is that a full sentence, "Furthermore, I am a certified laboratory directory by ABB"?
A. I am.
Q. Okay.
A. I think "am" is the verb.
Q. Now, when you go down to the next sentence, we see that you "obtained permit" in the last line. Is that right?
A. In the last line "obtained permit," yes.
Q. You don't use the word "a" to identify that it was a permit.
That's again your use of English. Is that correct?
A. I think it's -- if edited it would avoid it, it would be avoided.
Q. You would have put an "a" in there if it was edited?
A. Yes.
MR. HAMAD: You want to see my writing in Chinese?
MR. LEUCHTMAN: We are going through a lot

42

of trouble for English as a second language lecture from Mr. Stein
Q. And then as we go along in that sentence, you use the "construction for molecular testing since March."
I take it you obtained a permit for performing PGD for molecular testing in March, 2006?
A. In, yes.
Q. Instead of "since." Is that correct?
A. Yes.
Q. Okay. And if you had an editor you would have changed that to "in"?
A. Yes, I would.
Q. And likewise at the top of page --
A. Yes, in 2007.
Q. Okay. Then when we see the next sentence, "Beginning from 1995," you said "as I was the head."
Would you prefer to leave the "as" out and just say --
A. Agreed.
Q. And finally the last sentence in that paragraph, "cystic fibrosis covering more than a dozen of CF mutations"?
A. "Of".
Q. Now, when I compared your report with Dr. --
MR. LEUCHTMAN: Hughes.

43

Q. -- Hughes' report -- I am going to show you a copy of Dr. Hughes' report?
MR. LEUCHTMAN: Let's first ask foundationally -- this is an objection -- whether he has ever seen Dr. Hughes' report.
MR. STEIN: I can ask that question.
MR. LEUCHTMAN: Good. Go ahead.
Q. Have you ever seen Dr. Hughes' report?
MR. LEUCHTMAN: Before now?
A. No.
Q. Never read it?
A. No.
Q. Okay. Let's just take a look at your report and Dr. Hughes' report.
Do you see any similarity in the numbers one, two, three, four and five between your report and Dr. Hughes' report?
MR. LEUCHTMAN: I object to this line of questioning.
If he has never seen Hughes' report --
MR. STEIN: Okay. We have your objection on the record.
MR. LEUCHTMAN: -- then it's irrelevant --
MR. STEIN: Good.
MR. LEUCHTMAN: -- whether there are

44

similarities. The person to ask about this is Mark Hughes, and I am sure you will.
A. For the list, yes, I see similar.
Q. Okay. And do you notice they are not only similar, they are identical?
A. Looks like it.
Q. They are even identical to the point of having a comma after the "R" in Gary R. Cutting's name in No. 3. Is that correct?
A. Yes.
Q. Okay. So it's your testimony that Dr. Hughes did not provide you with the form and the content of that paragraph to include in your report. Is that right?
A. That's right.
Q. Okay. Now, you have indicated there that you have read the depositions of Chaya Grossbaum Volume 1 and 2 and Menachem Grossbaum. Is that correct?
A. Yes.
Q. Was there anything in that deposition that you found significant in writing your report of February 26, 2010?
A. The one significant thing I feel is that the couple was well counseled in -- I don't remember the particular dates, I think March, was it, 2004, I think, and the couple was really well informed, they are

45

intellectual, and they know lots of things and these are the couple I was very impressed the knowledge and including the second volume and the mother was doing, follow the instructions of helping the little child, it's very impressive. I think it's -- that's part of the way it strikes me.

Q. Well, that may have struck you, but where do you mention that anywhere in your report?

A. That I don't think that I -- I didn't think that it is relevant to my opinion.

Q. Do I understand then that the content of the depositions of Chaya Grossbaum, both volumes, and Menachem Grossbaum was not significant in formulating the opinions that you did to put in your letter. Is that correct?

MR. LEUCHTMAN: Objection to the form of the question.

MR. STEIN: Okay.

A. I wouldn't say it's insignificant.

It's just not part of what I will -- you know -- form this. It is significant, but it is not part that lead me to form the report.

Q. Is there anything in your report that is based on the deposition testimony of Chaya Grossbaum or Menachem Grossbaum?

46

A. I am sorry.

Could you repeat it.

Q. Yes.

Is there anything in your report that is based on the content of the depositions of Chaya Grossbaum or Menachem Grossbaum?

MR. LEUCHTMAN: I object to the form of the question.

MR. STEIN: What is wrong with the form of the question?

How is it, the form, inappropriate or improper, Mr. Leuchtman?

MR. LEUCHTMAN: Well, he read all the records. He formulated opinions based upon the entire record.

MR. STEIN: The form we are talking about.

MR. LEUCHTMAN: Yes.

MR. STEIN: What is wrong with the form of the question?

MR. LEUCHTMAN: What is wrong with the form of the question is that it assumes, without proper foundation, that this is this witness' thought process, that he has to make a direct linear connection between testimony he read and some part of his opinion as opposed to reading all the transcripts and formulating

47

opinion based upon that.

MR. STEIN: Okay.

Q. Can you answer my question?

What opinion that is contained in your letter of February 26, 2010, is based upon the content of the Grossbaum depositions?

MR. LEUCHTMAN: Same objection, and also as to the form.

I don't know what you are looking at, Mr. Hamad, but also as to the form based in whole or in part, the question is vague and ambiguous.

MR. HAMAD: I am looking at my e-mail, but I thought the question was what portions of the deposition transcript of Ms. Grossbaum did he look at.

MR. LEUCHTMAN: No.

MR. STEIN: That's not the question. Let's get the question answered.

I will have it read back. Do you want it read back?

MR. HAMAD: Please.

MR. STEIN: Would you read the question back, Mr. Fishman.

(Whereupon, the court reporter reads as requested.)

MR. HAMAD: I join in that objection to the

48

extent that I think it is vague somewhat.

MR. STEIN: Good.

Q. Can you answer the question?

A. I will say that at Page No. 3 --

Q. Yes?

A. -- that ADO and CVS issues.

Q. Show me what sentence on Page 3.

A. Page 3 second paragraph.

Q. Because --

A. Because of -- or the second sentences.

MR. HAMAD: Can you read that sentence into the record, Doctor?

A. "CVS has been shown to be very accurate. I know from my experience that Dr. Hughes and Genesis Genetics will not take on PGD of a couple if they will not agree in advance to CVF or amniocentesis, and this is appropriate and within accepted standards."

Q. Okay. Now, can you tell me which part of that sentence or that paragraph that consists of five lines is based on what is contained in the Grossbaum deposition?

A. I read Grossbaums deposition. I think they were told in the counseling, I think they understood the whole process and the consequences of ADO or technical failures.

I think that part is in there.

Q. Now you are telling me what the Grossbaums understood.

Is there any reference in that five lines to what the Grossbaums understood?

A. Right now I could not recollect which page of the Grossbaums. I believe it's in there.

Q. Okay. Do you have an index to the Grossbaums deposition?

A. So where should I look now?

Q. Is there an index on the back of the deposition?

A. Yes.

Q. So can you give me, using that index, can you show me where in the deposition you relied on information?

A. CVS, CVS, I have to look, go back, Page 72, so on 72 -- let me read, and so he told you the first conversation with him that there had been errors made in the past. He said there had been errors but it was -- he had a high, very high success rate. I think that is, probably that's the part they discussed errors.

I remember there must be mention, but I don't know where the page. I can spend time to look into details.

Q. Now, let's look at your report. Okay?

It says on that report, "Because of the ever present risk of ADO and other risk factors inherent in PGD CV S and amniocentesis are usually relied upon as a safety net." You said that?

A. Yes.

Q. In connection with your work at the laboratory you are not -- in your laboratory you are not involved at all with the patient. Is that correct?

A. How do you define that, "not involved with the patient"?

Q. You don't talk to the patient?

A. Directly.

Q. You said --

A. That's true. That's correct.

Q. So then you don't -- you are not involved in consenting the patient. Is that correct?

A. Not directly.

Q. Well, how are you indirectly involved other than the fact for you to have involvement there has to be consent obtained by others? Is that correct?

A. When we create a consent, we discuss -- it's an evolving process. We modify it a few times over the last ten years, so I was involved in writing or modifying the consent.

Q. Okay. Now, you say in the next sentence, "I know

from my experience that Dr. Hughes and Genesis Genetics will not take on PGD of a couple if they will not agree in advance to CVS or amniocentesis."

Can you tell me what experience you are referring to?

A. It's most likely from meeting, conversations and conference meetings and that sort of thing.

Q. And what meeting are you talking about?

A. Well, I had quite a few meetings -- you know -- at the same time. Once I can remember I went to China and he was invited to give lecture too there and we have that kind of interactions.

Q. And at that time he told you -- you now have a recollection of a conversation in which he told you that he doesn't do PGD unless the parents consent and agree to do either CVS or amnio. Is that right?

A. I do not remember that particular meeting we talked about, but I am just using the meeting as an example that we met often and he also gave lectures. We invited him at least once, maybe more, at least once, that he gave a lecture of a PGD in our institute.

Q. So then it's from -- are you telling me in that lecture at your institute, you heard him say that?

Is that what you are testifying to?

A. No.

Q. Okay.

A. I think on many occasions one of these occasions that we mentioned.

Q. So then when you refer to your experience you are referring to one occasion at a meeting he mentioned that. Is that right?

A. I would say at least -- at least the one.

Q. Okay. And from one meeting and a conversation with Dr. Hughes you conclude that that is your experience. Is that right?

A. Well, I wouldn't say only from one meeting.

Of course, I heard his talk many, many places and he gave lectures on many, many occasions.

Q. Give me some examples of where these many, many places were that he gave lectures that you were in attendance?

A. Well, ASRM.

Q. I am sorry?

A. American Society of Reproductive Medicine and he also gave lectures.

Q. Where was the lecture that you mentioned he gave a lecture?

A. I cannot recall where exactly and when, because it's definitely more than once.

Q. Okay. By the way, does your -- would you know if

53

any families had come to your clinic at Cornell Weill because Dr. Hughes refused to do their tests, since they were not going to do CVS or amnio?

A. That I don't know.

Q. And tell me, what other laboratories refused to do PGD studies if the family refuses to do CVS or amnio?

A. I don't recall.

These are the process, I think, now the genetic counselors are dealing with, so we have, I think as a referral lab we are dealing with RGI and we are dealing with Mark Hughes' lab, the Hughes' lab, and also Reprogenetics and we had also experience with a referral to Genzyme, and that's a FISH based PGD. They are no longer offering any testing anymore, but those are the main labs that we are dealing with.

Q. And why do you do referrals with those labs? Why do you deal with those labs?

A. Well, PGD is a very complex, particularly for single genes, there are thousands genes for each gene for cystic fibrosis. There are more than 1,000 mutations.

One lab will not be able to really offer everything, so, for example, as I said, our lab is limited with the resources. We can't do more than a thousand mutations, but for rare mutations, then we will

54

go to the larger lab. They offer more and they cover more mutations.

Q. Well, do you do the cystic fibrosis mutations?

A. Yes.

Q. Are there any cystic fibrosis mutations that you refer out to other laboratories?

A. Yes.

Q. Which ones?

A. Either Mark Hughes lab or RGI.

Q. What kind of -- what CVS mutations do you refer to Mark Hughes or --

MR. LEUCHTMAN: You mean V -- CF?

Q. CF. Yes. I am sorry.

A. Well the less common ones, less common ones. That's the main reason, and sometimes the patient has previous history or connections with RGI or Mark Hughes and they switch center and then we may, so it varies.

Q. Uh-huh. Do you do PGD analysis for the delta F508 cystic fibrosis mutation?

A. Yes, we do.

Q. You do PG mutations for G54 2X?

A. We do not that long. In early 2000, in early 2000 we didn't do it.

Q. When did you start doing G54 2X?

A. Well, G54 2X is the mutation that's not

55

recognized by enzyme called the restriction enzyme and you have to go through either whole sequencing or now we are using methodology called a mini sequencing, that -- that not depends on enzyme.

In the early days in the '90s, like the one that we publish cystic -- Sickle Cell anemia, that's recognized, the DNA sequences is recognized by a particular enzyme. That's the easy way to go for that mutation, but G45 2X is not, so we could not find the enzyme. In our lab it doesn't have, at that time, didn't have the machine, so later on we acquired a machine and then we start to work on that.

Q. When did you acquire the machine?

A. About early 2000.

Q. You mean 2001, 2002?

A. Likely.

Q. Now, are you involved in the process of referring to other labs embryos for PGD study?

MR. LEUCHTMAN: You mean cells biopsy?

MR. STEIN: That's what I mean.

MR. LEUCHTMAN: I am sorry, Lew.

MR. STEIN: I am sorry, Mr. Leuchtman, if the witness didn't understand what I mean, then he can tell me.

I am using a frame of reference.

56

MR. LEUCHTMAN: Well, you know --

MR. STEIN: I am trying to shorten the words. If he finds it difficult to understand what I am talking about, then he will tell me. That was his instruction at the beginning.

For you to intrude on the questioning is inappropriate.

MR. LEUCHTMAN: I am not suggesting any answer. You know my intrusion is not coaching. It's just simply somebody is going to read this transcript and if the question isn't clarified, they are going to think and if the witness doesn't catch the error in it, it is an error, then someone could be misled. Maybe that's a matter of indifference to you. It isn't to us.

I am sorry.

MR. STEIN: I don't characterize it as --

Q. You understand, Doctor, when we talk about doing PGD studies on embryos, those studies primarily involve single cell analysis.

Do you understand that?

A. Yes.

Q. My question -- so when I simply refer to the embryo, you know I am referring to the single cell analysis. You understand that. Correct?

A. Yes.

57

Q. Okay. Now, my question again, when you send out blastomeres from an embryo for analysis at either the laboratories that you mentioned, are you involved in that process?

A. Do you mean involved in the procedure or involving the prearrangement for that particular couple?

Q. Let's start with you make the arrangement with the laboratory?

A. For -- I am sorry -- I interrupt.

For the arrangement the genetic counselors will arrange which lab, whether it's Chicago or Detroit or any other places, but when it's an actual case, most likely I am the person to do the biopsy and I have a staff or assistant in helping -- we have very strict procedures -- you know -- masks and all of these to avoid contaminations, and then she will do the receiving of the single cell and we all double-check the numbers and then we ship.

So in that sense, I am involved.

Q. Okay. Now, when the report comes back, are you involved in getting the report?

A. I am part of receiving report. We have several people receiving the report. I am one of those, and mainly the embryologic lab receives the reports and they will at the time of the transfer discuss, well, the

58

physician, attending, and then the patient, the embryologist.

I am involved if there is any technical question that I can help to explain, then I will be involved.

Q. You do not routinely receive the reports from referral laboratories. Is that correct?

A. What do you mean "routinely"?

Q. On each occasion when you send specimens for PGD analysis to a referral laboratory such as Genesis Genetics or Chicago and there is a report that comes back from those laboratories, do you routinely see those reports when they come back?

A. Yes.

Q. Okay. And then you place them in a file in the chart?

A. Right.

Q. And when they come back and you place them in the chart, do they usually carry with them some form of transmittal indication, date, time of the transmittal?

A. Yes.

Q. Now, in your review of the Grossbaums' chart at NYU, I take it you reviewed that chart. Is that correct?

A. Yes.

Q. Did you see that there were two reports that came

59

back from Genesis Genetics?

MR. HAMAD: Objection to form.

The NYU chart two reports?

MR. STEIN: Pardon me?

Q. Did you see two reports from Genesis Genetics by Dr. Hughes regarding the Grossbaums that were sent to NYU?

A. Yes.

Q. Okay. You saw the two in the Genesis Genetics record. Isn't that so?

A. Yes.

Q. You only saw one in the NYU record. Isn't that so?

A. That I don't recall. I have to double-check it.

Q. Why don't you double-check.

MR. LEUCHTMAN: Withdrawn.

I take it back. I should have waited.

I am sorry.

MR. STEIN: That's all right.

MR. LEUCHTMAN: I will stipulate.

I think you want to ask the question anyway that NYU records did not contain Dr. Hughes' second report for whatever reason.

A. Okay. I have NYU's report here.

No, I don't see it.

60

Q. Okay. Let me show you what purports to be a report from Genesis Genetics to NYU showing the result of the PGD analysis for the Grossbaums.

Do you see that?

A. Yes, I see it.

Q. Behind that in the chart is something called a transmittal verification report?

A. Yes, I see it.

Q. Is it customary for you to receive, when you receive reports from the laboratories that you refer to, a transmittal verification report?

A. We will have that fax sheets, yes.

Q. Okay. And that is in the process a method of confirming that the report has been sent and received.

Isn't that why you have the transmittal verification report?

A. Right.

Q. And it's standard procedure for the report when it's transmitted to have a transmittal verification report made a part of the chart. Isn't that so?

MR. HAMAD: By both the center and the receiver, both the receiver of the reports.

Q. The receiver of the -- when you refer to a laboratory for a PGD analysis and you receive the report, you customarily and routinely receive a

transmittal verification report. Isn't that so?
A. That's in the fax machine.
Q. And you put it in a chart at your lab. Is that so?
A. Actually, I am not sure we have -- our fax machine had this piece.
Our fax machine -- when we send we definitely have this sheet, but receiving I don't think we have that kind of report.
Q. Okay.
MR. HAMAD: I thought you were asking if the sender sends him that copy as well.
MR. STEIN: Yes.
Q. Does the sender send you that copy?
MR. LEUCHTMAN: That's what he is asking.
Q. That's what I am asking.
A. The sender.
Q. When you receive the report, do you have the verification of transmittal included in your chart?
A. The sender does not send this type of --
Q. Okay. That's all I am asking.
Now, did you mention Genesis Genetics? You, so to speak, refer to that laboratory?
A. Yes.
Q. And you refer to the RGI laboratory in Chicago?

A. Yes.
Q. Can you tell me whether you still refer to both of those laboratories?
A. Yes.
Q. And is there any basis on which you choose one or the other?
A. There is several factors considered.
The main factor who offers that particular service.
Sometimes one offers and the other one does not -- is not -- hasn't yet established the procedure and then, obviously, we will go that way.
Q. Okay. And can you give me an example of that, what type of service one offers and the other does not?
A. Well, there are thousands of mutations. We will check this particular one.
Let's say it's a rare one and not common one and RGI may already have that mutation established and the Genesis may not, then we will definitely go to RGI or vice-versa.
Q. How do you determine whether or not a particular laboratory has the analysis established?
A. In the early days when I was involved directly, then I call them and ask them, and a genetic counselor, they contact their genetic counselor to see if they have

in their inventory.
Q. Tell me what you mean by the "early days" when you were involved.
A. Well, because the early days, in the '90s, we do only 30, 40 cases a year and we don't have -- we didn't even have a genetic counselor hired directly in our center. Now we have our own in the center and those are the early days, '90s, I would say.
Q. And did RGI do linkage analysis in early 2000?
A. In 2000 we have very few cases sent to RGI.
Q. Okay.
A. And we started collaborating or work with Mark Hughes earlier than RGI.
Q. Say that again, please.
A. We started to refer cases to Mark Hughes many years earlier than to RGI.
Q. And does Genesis Genetics do linkage analysis today?
A. Yes.
Q. Can you tell me when Genesis Genetics first started to do linkage analysis?
A. I don't recall any specific year.
Q. Was it as early as 2001, 2002?
A. Likely not -- you know -- I don't have the specific dates.

Q. All right.
Before I leave the deposition transcripts, other than the deposition of Dr. Hughes, was there anything in the deposition of Dr. Frederick Licciardi that you relied on in forming the opinions that are contained in your report of February 26th?
MR. HAMAD: Objection to form.
MR. LEUCHTMAN: Other than the deposition of Dr. Hughes, is there anything in the deposition of Dr. Licciardi?
I object to the form.
MR. STEIN: I agree.
Q. Is there anything in the deposition of Dr. Licciardi that you relied on in formulating the opinions contained in your report of February 26th?
A. I read his deposition, but I don't think there is much to rely on his deposition.
Q. Okay. Was there anything in the deposition of Dr. James Grifo that you relied on in formulating the opinions contained in your report?
A. Well, one thing I share with Dr. Grifo is ADO and misdiagnosis, that's the one as a PGD. Any people working in PGD, that's really in our mind all the time. We really -- that's really exactly what we are trying to avoid and we try to help these couples. I share

65

completely, I agree with Dr. Grifo.

Q. Even though you may agree with Dr. Grifo, did you rely solely on the deposition of Dr. Grifo to formulate that opinion?

MR. HAMAD: Objection to form.

I don't think he says he "relied on his deposition."

A. I don't think I relied on his deposition.

Q. Okay. So then is it fair to say that there was nothing specifically in Dr. Grifo's deposition that you relied on to formulate the opinions in your report?

A. Well, I am not too sure.

Well, I don't think it's a main source of forming, I would say, forming my opinion --

Q. Okay.

A. -- in the report.

Q. So do I understand that you would have formulated the same opinions if you had never read Dr. Grifo's deposition? Is that correct?

A. I would.

Q. Is that correct?

A. Yes.

Q. Okay. How about -- pardon me -- the deposition of Ms. Alexis Adler, was there anything contained in the deposition of Alexis Adler that you relied on to

66

formulate your -- the opinions contained in your report?

A. I don't think there is specific -- any specific points.

Q. Okay. So the answer is no, there is nothing that you relied on in Alexis Adler's deposition to formulate your report. Is that correct?

A. If you say "nothing," I would disagree, but it's not major.

Q. Okay. Show me what is contained -- show me in your report what you relied on with Alexis Adler to supply by way of information for you to rely on in formulating your report?

MR. HAMAD: Objection to form.

I think you misstate his prior testimony.

I don't think he said he "relied" on it.

MR. STEIN: I don't think he said it either. I wasn't clear, so I want to be very clear.

A. Well, the embryology part, I think -- let me see, is it the embryology part -- I said it's not main source, but all of these depositions, they say -- they provide or probably influence my report.

I wouldn't -- it's hard to pick up that specific one.

Q. Show me in your report what you say was based on, in any way, on what is in Alexis Adler's deposition?

67

A. I wouldn't say any specifics.

Q. Okay.

A. There is no specific point.

Q. And likewise for the deposition of Kaycian Brown and Imelda Weill, is it also true that you did not rely on anything contained in their depositions to formulate the opinions contained in your report? Isn't that so?

A. I would agree.

Q. Okay. Now, Doctor, do you agree that PGD involving couples with compound heterozygous has an acceptable high error rate?

A. I disagree on "acceptable." I think that's -- it depends on different couples.

Q. Well --

A. Definition of "unacceptable."

Q. Well, do couples who have compound heterozygous in their genetic make up --

MR. LEUCHTMAN: Heterozygous?

Q. -- have a higher error rate than other mutations?

MR. HAMAD: I am going to object to form.

MR. LEUCHTMAN: Same here.

A. Similar as autosome dominant inheritance, so it would not more complex than that one.

Q. Well, autosome -- autosome dominant --

A. Which is a 50/50.

68

Q. Okay. So couples who have mutations that are not described as compound heterozygous --

MR. LEUCHTMAN: Heterozygous.

MR. STEIN: Thank you, Mr. Leuchtman. I will repeat the question.

Q. Couples that have cystic fibrosis mutations that are not described as compound heterozygosity have a 25 percent chance of having an affected baby. Isn't that right?

MR. LEUCHTMAN: Objection as to the form.

MR. STEIN: Okay.

A. Not heterozygosity and have a 25 percent, if they share the same mutation you mean?

Q. If they are not heterozygous, compound heterozygous, do they have a 25 percent chance of having an affected baby?

A. Yes. You are correct.

Q. A dominant recessive -- withdraw that question.

People who have heterozygous-dominant mutation have a 50 percent chance. Is that correct?

A. Yes, dominant disorders, yes.

Q. Okay. Are any cystic fibrosis mutations dominant?

A. No, cystic fibrosis is recessive.

Q. So do -- in the cystic fibrosis mutation

69

analysis, do couples who have compound heterozygous mutations have a greater risk of having an affected baby than those people who do not have compound heterozygosity mutations?

A. It's more complex, yes.

Q. You also agree that ADO, which is allele drop out is the most likely cause of reported errors in PGD of cystic fibrosis in which affected compound heterozygous embryos were misdiagnosed as carrier embryos because the analysis used can only detect one of the inherited mutations?

A. I am sorry.

Could you repeat it again.

MR. LEUCHTMAN: I guess we have this, Lew: I am obliged to object to this question as leading, a general statement from some specific article.

MR. STEIN: That's fine.

MR. HAMAD: I am not going to object.

I am going to ask where you are reading that from, Lew.

MR. STEIN: We will get there.

Q. Are you familiar with a review article by Alan R. Thornhill and Karen Snow?

A. I read it before.

Q. And do you know Alan R. Thornhill?

70

A. Yes, I know him.

Q. How do you know him?

A. Through professional meetings.

Q. Okay. And do you know where he is located?

A. He is in London now.

Q. Okay. And where was he in the year 2002?

A. That I don't know.

Q. Was he ever at the Mayo Clinic?

A. Yes, he was.

Q. Okay. And do you know Karen Snow?

A. Karen Snow, no, I don't.

Q. Is Alan R. Thornhill a respected authority in PGD?

A. I am not sure if it's authority, but definitely respected scientist.

Q. Okay. And is his publications relied upon by people in the genetic and IVF field?

MR. HAMAD: Objection to form, the IVF.

How can this physician speak about the IVF.

MR. LEUCHTMAN: I will object as to foundation.

A. What we read and we value his intellectual and also his scientific insights.

Q. And you are familiar with his review article -- by the way, what journals do you read?

71

A. I read, well, Human Reproduction Fertility Sterility, Molecular Human Reproduction, and many. Then plus Nature and Science. These are all New England Journal of Medicine, American Journal, which is Journal of American Medical Association and, I guess -- I think a lot, lots more.

Q. Do you read the Journal of Molecular Diagnostics?

A. That particular journal, I am not a regular reader, no.

Q. Do you read it from time to time?

A. If that's usually we search the particular field and then we will go to that journal.

Q. Okay. Do you agree with Dr. Thornhill's statement in his review article published in the Journal of Elective Diagnostics in February of 2002, when at Page 14, he writes, "Another problem unique to single cell PCR is that of allele drop out, a phenomenon where only one of the two alleles present is successfully amplified"?

A. Yes, I agree with that.

Q. Do you agree with his statements -- his statement that "in addition to reducing ADO strategies have been posed to increase the detection of ADO"?

A. Was proposed, yes.

Q. Okay. "One such strategy is the use of linked

72

markers which simultaneously controls for condemnation, use of one or two linked markers reduces undetected ADO by approximately 50 percent and 75 percent respectively and with three linked markers, ADO is virtually always detected."

Do you agree with that?

A. I would agree with the first part, but the second part, I think, it depends how good these markers, how good you design, and how good, how well positioned the marker.

The markers is a tricky issue. You wanted to see introgenic, which is within the gene. That's close to the gene, because there is a phenomenon called a recombination, so if a marker is far away, there is a recombination occurs that will make it even wrong diagnosis, so you have to recognize that and introgenic markers sometimes are less polymorphic. Polymorphic means whether it applies to this particular couple sometimes if the male partner and female partner shares the same size, when we determine the markers, then that marker is not useful, so we have to find a particular marker for particular couple, so, I think, it depends, so, I think, I agree with him the first part, but not the second part. I think a little --

Q. Well, would you agree with this statement that he

makes, "The use of linked markers carries considerable advantages, not only from the point of view of reducing the possibility of misdiagnosis, but also by potentially increasing the number of embryos available for transplant"?

A. I think the second part, again, it's not necessarily. The first part, yes, increase the accuracy.

Q. Okay. And that knowledge was published in 2001, November 2001.

Would you agree that the state of knowledge in the community doing PGD about the advantage of having linkage analysis was well known by November 2001?

A. Yes, the concept and the use, yes, when we do the retinoblastoma, and we tried using linkage marker.

Q. And it's true also that Chicago, RGI in Chicago, was using linkage analysis in 2000. Isn't that true?

A. I read their publications.

Q. Yes. Okay.

So, Doctor, if under hypothetical circumstances Dr. Hughes and Genesis Genetics was not using linked markers in 2004 and Chicago and RGI was using linked markers, wouldn't it have been better for a couple to be referred for analysis to Chicago than to Detroit?

MR. LEUCHTMAN: Objection to form.

MR. HAMAD Objection to form.

A. This is really a complicated issue.

To referring to what referral lab is not only determined by what the procedure they provide. There is also a link historically where do you usually go and which lab perform better.

I think -- we have not have a close kind of referral in '90s with RGI. I would not speculate -- you know -- any reasons, but we did not have a close referral collaboration with RGI.

MR. HAMAD: I am also going to put a belated objection to that question.

It mistakes the doctor's answers. I think the doctor never said that it was accepted. He did not say it was accepted. He said it was done. He used that to argue it was accepted. It's a difference.

MR. STEIN: You say it is different, your testimony, we will take your deposition to determine what is a difference.

MR. HAMAD: Off the record.

(Whereupon, a discussion takes place off the record.)

THE WITNESS: If I may, I should add sometimes a patient has a say.

For example, they started to build up,

already started the case, and they paid for pretest and even with our suggestion they may still choose the one that they already established a relationship with the lab.

MR. LEUCHTMAN: Off the record one second.

(Whereupon, a discussion takes place off the record.)

Q. Whether the use of linkage analysis, that was reported as early as 1997, wasn't it, Doctor?

A. I don't recall what exactly. I think in the prenatal field it probably even earlier.

Q. Have you attended the annual meetings of the international working group of preimplantation genetics?

A. The working group, yes, now it's called PDDIS, yes, I did. Not every year.

Q. Were you a member of the working group?

A. I am a member of that society. Now it's called a society.

Q. When did you become a member of that group?

A. I don't recall when exactly the timing. Probably early 2000.

Q. Not in the '90S?

A. Well, I went -- actually, that's the place where I met the first time, I believe, with Dr. Strom, that is in Chicago. That's the same society evolved.

Q. And did you go to Rio de Janeiro, Brazil for the sixth annual meeting?

A. No, I didn't.

Q. Did you get -- did you review the reports of those working groups on a regular basis?

A. Yes, sir.

Q. And is it likely that you would have read the Journal of Assisted Reproduction and Genetics, Volume 14 No. 2 in 1997?

A. Most likely. That's the journal also I regular read.

Q. Okay. Now, Doctor, you mentioned RGI and you mentioned Hughes' group and Genesis Genetics.

What other laboratories were doing PGD analysis at that time -- back in the early 2000's? Do you know?

A. I am sorry.

Where or what other.

Q. What other laboratories were doing PGD? You were doing it yourself, but that was not open for referral by other clinics.

A. Right.

Q. But what other laboratories were accepting referrals at that time?

A. Reprogenetics.

Q. And where are they located?

77

A. **In New Jersey.**
Q. Okay. Were they doing single cell blastomere analysis?
A. **Well, I don't know the details, but I don't think they did that early 2000.**
MR. LEUCHTMAN: Single cell?
MR. STEIN: Yes.
Q. They were doing FISH?
A. **They were doing FISH because my former colleague he is expert in FISH.**
Q. Now, what other laboratories do you know of that was accepting referrals?
A. **I don't think -- although I can't be sure -- I know what is it, one in Virginia, Genetic -- is that called Genetic Genesis? There is one.**
Q. Do you know --
A. **In Virginia.**
Q. Do you know who is associated with the one in Virginia?
A. **GIVF. Well, in short, it's called GIVF.**
Q. What specialist was involved? Do you know the name of the man that --
A. **Dr. Shulman. Shulman.**
Q. -- Was in charge? Okay.
A. **I am not 100 percent sure, but somewhere very**

78

close. He is the one doing it, and then Jones Institute.
Q. Okay where are they located?
A. **Virginia.**
Q. And who is associated with the Jones Institute, what individual was the director?
A. **Susan. I know her fairly well. Susan is the person, the first name, Gatling, started from G. And she is -- she is the one doing PGD for long, long time actually. They are also similar like us. It's also economic. I don't know if they ever receive from outside.**
Q. That's part --
A. **Jones Institute.**
Q. Is it part of an academic institution?
A. **Yes.**
Q. Which one, University of Virginia?
A. **No. I don't believe it's University of Virginia.**
Q. But it's a major teaching university?
A. **Yes, it's a teaching university.**
Q. Okay. And what other -- were there any other laboratories at the time?
A. **In early 2000?**
Q. Yes.
A. **There are a few small places attempting, but I**

79

don't think they are major.
Q. Were there any other Medical Center based laboratories like Cornell Weill who were doing it as you would describe, in-house and not accepting referrals that you knew of at that time?
A. **Not that I know major. They all try to establish it, but there is no really major ones.**
MR. STEIN: Okay. I think this is a good time to take a break.
MR. LEUCHTMAN: Okay. Thanks.
(Whereupon, a short recess is taken.)
Q. Doctor, I am just referring to one more statement that Mr. Thornhill -- Dr. Thornhill had back in his publication that we were referring to.
Do you agree with this statement, "For compound heterozygous or autosomal-dominant conditions, the consequences of ADO can be catastrophic as misdiagnosis and subsequent transfer of affected embryos can occur."
Do you agree with that?
A. **Agree, yes. Yes.**
Q. In fact, it goes on, "Indeed ADO is the most likely cause of reported errors in PGD of cystic fibrosis in which affected compound heterozygous embryos were misdiagnosed as carrier embryos because the

80

analysis used could only detect one of the inherited mutations."
Do you agree with that?
A. **I think that was the understanding or at least the view in the year he wrote the paper, but it's more complex than just ADO.**
Q. Do you agree?
A. **So --**
Q. Do you agree that is a completely inaccurate statement?
MR. LEUCHTMAN: Let him finish his answer.
Q. I am sorry.
A. **I don't think that is a complete description of a misdiagnosis. I think it is part of the reason for misdiagnosis.**
Q. All right.
And linkage analysis you would recommended as a method for improving the accuracy in that type of situation where you have compound heterozygous embryos.
Do you agree?
A. **Yes or autosome dominant as well.**
Q. Well, here we are not dealing with autosomal-dominant.
We are dealing here with cystic fibrosis, a recessive gene in which we have with the Grossbaums, a

compound heterozygous mutation.

Do you agree that we have that kind of mutation with the Grossbaums?

A. For this case, yes, I agree.

Q. Do you agree that ADO has been shown by many authors to be at least 20 percent and some authors have shown it as high as 70 percent?

MR. HAMAD: Objection to form.

MR. LEUCHTMAN: Of what?

Q. I said ADO has been shown by many authors to be at least 20 percent and some authors have shown it as high as 70 percent.

Do you agree with that.

A. I disagree.

MR. LEUCHTMAN: I object.

It's an incomplete statement.

MR. STEIN: Only if the doctor says it's incomplete, if he can't answer the question and he says it's incomplete.

MR. HAMAD: I think he answered it. He disagrees. He was going to explain why he disagrees.

Q. You disagree?

A. I disagree.

MR. HAMAD: He was explaining in the middle of why he disagrees.

Q. What does the literature report is the rate of ADO in analyzing single cell blastomeres for cystic fibrosis?

A. Well, ADO, I think we are still trying, struggling with ADO with all the possible methodology and, I think, still we are trying to investigate what is the extent, how to prevent it or at least reduce.

I think the statement from 20 percent to 70 percent to my knowledge, is overstatement, and also we look at our own data. I think it's not that high.

Some of it is, because, for example, one of the reason is the poor embryo. When embryo quality is poor, one of the poor embryo is due to aneuploidy. Aneuploidy may cause ADO as well. Little a more likely existing in the slow arrested embryos and in human embryo field what is common is very difficult to get good embryo as a research material, because very few people will be able to donate their healthy embryos.

So in the literature the common issue the centers are able to get the material from arrested three days, on Day 3, four cells, that's discarded, and then they do experiment. They show huge percentage, 70 percent. That's the publication, but these are not real ADO in PGD cases, so I disagree with that number.

Q. Do you agree with the number around 27 percent?

MR. HAMAD: Objection to form.

A. I think it's too high.

Q. Too high.

Are you familiar with the Atlas of Preimplantation Genetic Diagnosis that was published by the Chicago group around 2000?

A. I saw this.

Q. You saw it?

A. Yes.

Q. And you saw it because it was part of the accumulated literature and materials in the PGD industry, so to speak. Is that correct?

A. Yes.

Q. All right.

Let me show you Page 152 of the Atlas.

Do you see there a graph for ADO?

A. Okay. Figure 5, yes, exactly.

Q. What number is that graph?

A. NCF, it says, 27.1. It's a blastoma.

Q. Do you disagree with that statistic?

A. I disagree.

Q. Okay.

A. I think that's from early studies and I don't know where the material was from.

Q. Well, this manual is published in the year 2000.

Do you recognize that?

A. Yes.

Q. And you disagree with this publication to that extent. Is that right?

MR. HAMAD: Objection to form.

A. Yes, I disagree.

Q. Okay.

MR. LEUCHTMAN: I also disagree, or object to the characterization of it as a "manual."

MR. STEIN: It's called an Atlas.

You disagree this is called an Atlas.

MR. LEUCHTMAN: No, I disagree with your characterization as a "manual."

Stay with me, Lew.

MR. STEIN: All right. All right.

What about -- why do you disagree with the characterization as a manual.

MR. LEUCHTMAN: Because it isn't a manual.

A manual tells you how to do things. An Atlas is a sort of a publication. I realize we have different standards of precision.

Q. Dr. Xu, do you know what the risk is of misdiagnosis in the analysis of blastomeres by single cell studies in genetic laboratories in percentage terms?

85

A. It is not that easy to pinpoint and the outcome from the published literature is misdiagnosed as a born child is one to two percent if you look at the literature.

MR. LEUCHTMAN: But I will belatedly object to the question as vague and ambiguous as to time and circumstances.

MR. HAMAD: I will join in that objection.

You are referring to actual births or I mean there could be 80 over 40.

Q. Are you familiar with the literature published by the group headed by Dr. Gresen?

A. Yes, I read it before.

Q. Okay. And he published an article in 2000 entitled Multiplex PCR of Polymorphic markers flanking the CFTR gene?

Do you recall that publication?

A. Yes.

Q. Is that type of publication relied on by people in the PGD business, so to speak?

A. Certainly we read and we use that as information, yes.

Q. Now, in Dr. Gresen's article there is a statement, "The risk of misdiagnosis equals a chance of a double recombination between flanking markers and is

86

less than 0.05 percent.

Do you recall reading that?

A. I don't recall reading that, but I think it's not accurate, because there are so many markers. The distance of the markers determine the recombination, so it is too general statement.

Q. Okay. Do you know what the rate of misdiagnosis for CF PGD at Chicago has been since 2000?

A. I don't know.

Q. Have you heard of any reported misdiagnosis out of Chicago since 2000?

A. I have not heard.

Q. Okay. Have you heard of any reported misdiagnosis out of Genetic Genesis Laboratories since 2000?

MR. LEUCHTMAN: Obviously, we are dealing with one.

MR. STEIN: I know.

MR. LEUCHTMAN: I am glad you know.

MR. STEIN: I know we are dealing with one. He knows we are dealing with one.

A. Not that I know.

Q. Pardon me?

A. Not that I know.

Q. You don't know of any other one other than this

87

one. Is that right?

A. Right.

Q. Do you agree that if you have three linked markers, ADO is virtually always detected?

A. I disagree.

Q. Okay. Do you have an opinion as to whether at the time that the couple, that is, the Grossbaums, presented for PGD, they should have been informed that this particular situation is extremely risky when performed on blastomere biopsies because of the risk of allele drop out?

MR. HAMAD: Objection to form.

MR. LEUCHTMAN: Same. I will join in that.

A. I disagree.

I don't think extremely risky. That I disagree.

I think PGD always there is a risk for PGD, but extremely risk for heterozygous compound mutation the risk is a little higher, but it's not extreme.

Q. How much higher is it?

A. Well, it depends on ADOs. How do you define what's the estimation of ADOs?

Q. What is your estimation of ADO?

A. Well, to my knowledge 20 percent is over estimate when you have good embryos or biopsy isn't complete.

By the biopsy if you have a good person to

88

perform the biopsy, the cells intact, it will be less likely to have ADO compared to -- if you pull a cell, the cell, the membrane dissolved, then it also could contribute ADO, so, I think, ADO with 20 percent is overstated.

Q. All right.

What do you think -- well, do you have an opinion as to what this couple's risk of ADO was with conditions shown by Dr. Hughes in his report?

A. We quote with ADO of a five to ten percent. That's what I current in my estimate.

Q. From compound heterozygous patients you will quote an ADO risk of five to ten percent?

A. ADO actually defines for a specific allele, so this allele is five percent, five to ten, and that allele, for a test, it's not -- not a compound or single mutation, so it's specifically refers to that particular allele.

Q. And that particular allele is identified as which allele?

A. Whichever. In this case, of course, it's defined F548 or G542X.

Q. And should the couple have been told to do a single cell blastomere study that they had a higher risk than the couples who don't have that compound

89

heterozygous circumstance?
MR. HAMAD: Objection to form.
MR. LEUCHTMAN: Same.
A. I think it should be informed and I understand that's what it did.
Q. Okay. And who informed them, that you understand?
A. What I understand, Dr. Hughes.
Q. Do you understand Dr. Hughes told them they had a higher risk because they were compound heterozygous than the average? You understand he told them that?
MR. HAMAD: Objection to form.
MR. LEUCHTMAN: Same.
A. In that Dr. Hughes notes I see the explanation of all the risks.
Q. Okay. Can you tell me where he told them they had an increased risk because they were compound heterozygous in his notes?
MR. HAMAD: Objection to form.
MR. LEUCHTMAN: Same.
A. I can see on Page 2.
This is a complicated two different mutation test -- tested -- excuse me -- simultaneously in one cell.
I think that will --

90

Q. That will do it?
A. Implies -- well, obviously -- not obviously -- I think when the real conversation occurs, there will be more than just that sentence, but that sentence indicates it's a complicated two different mutation -- mutations tested.
Q. Should he have told them -- withdraw that.
Is there any indication he told them that there was a type of an analysis called linkage analysis that could improve the accuracy and reduce the risk of misdiagnosis?
A. I am not sure if this is in his notes, linkage analysis.
Q. Pardon me?
A. I didn't find that for linkage analysis, anything noted here.
Q. Okay. And assuming that there were laboratories that were doing linkage analysis in 2004, should Dr. Hughes have told the Grossbaums that they could get a more accurate analysis with linkage analysis and a reduced risk of misdiagnosis if they went to a different laboratory?
A. As I mentioned before, I think referring or the decision whether to go to a lab, it depends on many other factors. It's not only one that what test they

91

are offering.
Q. What are the other factors that could determine whether or not you go to a laboratory other than the one issue of whether the laboratory does linkage analysis or not, what are the other factors?
A. Well, IVF clinics, the working relationship with the lab. As I also indicated earlier on that we have been doing with Dr. Hughes in the '90s, we have very few cases with RGI, so I think that's one.
Q. What is it about the working relationship that would suggest that they be sent to one laboratory versus the other? What do you mean by "working relationship"?
MR. HAMAD: Objection to form.
A. Well, perhaps the physicians know Dr. Hughes, would be one.
Q. What in the knowledge of the physicians knowing a doctor have to do with the choice of what laboratory they should go to? Tell me what in that relationship is significant to you.
MR. HAMAD: I am going to object to the form of the question. This is a hypothetical. It has nothing to do with the facts in this case, considering these patients came in.
MR. STEIN: You made your objection.
MR. HAMAD: I am sorry.

92

Q. Go ahead.
A. The doctors may go to a scientific meeting, learn who is performing what kind of a test. Then they will go for that particular test or go to that particular lab.
Q. In your opinion the laboratory had no obligation to advise the couple that there could be a type of analysis done for them which would reduce the risk of misdiagnosis and that type of analysis was not being offered by Genesis Genetics?
MR. HAMAD: Objection to form.
MR. LEUCHTMAN: Same here.
MR. HAMAD: This again, this is a hypothetical, and I think you should term it as a hypothetical.
In this case I think the facts are clear these patients came in already having contacted Dr. Hughes before they saw the laboratory. It has nothing to do with this case.
MR. STEIN: Fine.
Q. Go ahead.
A. Saying it is obligations, I think it depends on what kind of knowledge they have.
I don't think in 2000 or even as of today, there is a clear publication which lab has a better or more

93

accurate, so I don't think the information is that regularly available.

Q. All right.

Let's be more specific.

From the knowledge that you had in 2004 in June when the Grossbaums were undergoing PGD, RGI in Chicago was doing linkage analysis. Isn't that so?

MR. HAMAD: Objection to form.

A. I was not that clearly aware of that.

Q. All right.

A. At least from my -- you know -- from my point of view.

Q. Okay. Was it important from your point of view to know in 2004 whether there was laboratories doing linkage analysis for cystic fibrosis compound heterozygous couples?

A. It would be important to know, but there is not a mechanism there.

American Society of Reproductive Medicine just started under the ASRM, a society called Society for Assisted Reproductive Technology. SART, and they start to collect the data only two or three years ago. They tried to start to build up that data base, so can inform different centers.

That is not even on-line yet. Right now it's not

94

available, but they recognize that as indicated it's a critical issue, so they just started. We started to feed in the data, so I hope it will be soon or in the near future that kind of information will be available, but that wasn't available publicly or -- you know -- unless you go to the meetings there might be talk, but it's not a data base you can easily search for.

Q. Turning to your report, Doctor, and you state, "In 2004, not all the laboratories were using linkage markers and not for every single mutation."

In other words, multiplex PCR was not the standard in 2004. Is that right?

A. Yes.

Q. All right.

So what laboratories were not using multiplex PCR in 2004?

MR. HAMAD: Besides Genesis?

MR. LEUCHTMAN: And to a large extent his own.

A. It is an evolving process and we started to use that linkage marker in the mid 2000, but then we have to make a decision which disease we are going to start with and according to our statistics, cystic fibrosis is the major one because it's a more common, although we started reported sickle cell anemia.

95

Q. Doctor, can I direct your attention to the specific statement you made?

A. Uh-huh.

Q. You did make the statement, did you not --

A. Yes.

Q. -- that in 2004, "Not all the laboratories were using linkage markers and not for every single mutation." Okay?

A. Yes.

Q. You said that?

A. Yes.

Q. Okay. Now, we are dealing here with the cystic fibrosis --

A. Yes.

Q. -- mutation, and we are dealing here with delta 508 and G542?

A. Right.

Q. Can you tell me what laboratories were not using multiplex PCR in 2004?

A. That I don't know. I think -- I don't know what exactly -- Jones Institute was using and I don't know whether Reprogenetics was using and we started to build these, but we have not routinely used it.

Q. So then if you didn't know what Reprogenetics was doing, and you didn't know what Jones was doing, how can

96

you say that not all laboratories were using the mutation?

A. Well, one of the things I think even as of 2009, that's not a cystic fibrosis, if you think it's relevant or not, I will not use that example, but if you allow me, in New Jersey I think a lab they are offering for myotonic dystrophy, which is also dominant gene. They use the one marker, not three, as -- you know -- recommended in 2000, so, I think, my point is that using of a marker is a process, not just you turn on and you have to use and you will be able to use all the markers.

Q. You keep talking about an evolving process, however you agree the literature by 2000 had clearly indicated and defined linkage analysis. Isn't that so?

MR. HAMAD: Objection to form.

MR. LEUCHTMAN: Same.

A. Not defined. They started to recognize use and recommend the use of a linkage markers.

Q. And if it was recommended in 2000, do you know of laboratories -- well, that were using it in 2004? Do you know what laboratories were using linkage markers for cystic fibrosis with patients, delta 508 and G542, what laboratories were using linkage markers?

A. I am not aware of which ones were using it. It's likely RGI.

97

I don't think we send at that time to RGI yet, but I have to check our record.

Q. Well, whether you were sending them there or not, from your meetings and from your awareness of what they were publishing by way of analysis in 2000, did you not assume they were doing it for those mutations based on the literature and based on their Atlas and the information that they published?

A. I think they publish the workers it's usually the leading -- leading centers '01 of these studies, but to implement it takes time.

For example, I just -- if you allow me -- people started to using micro array technology to detect 24 chromosomes and it's proposed a few years ago, but still in the process of not every lab is using that technology. They already show in the publication you can detect 24 chromosomes, but very few labs are doing it now offering for clinical use, so from the publication to clinical use it takes some time to implement.

Q. Now, Doctor, let's turn to the report that Genesis Genetics sent to NYU.

Do you have a copy of it?

A. Yes, I have.

Q. In his report Dr. Hughes said that sample No. 8

98

was okay for transfer. Is that correct?

A. Yes.

Q. And No. 10 was okay for transfer. Is that correct?

A. Yes.

Q. He did not indicate that any of the others were okay for transfer?

MR. HAMAD: Objection to form.

Q. Isn't that correct?

MR. HAMAD: He did not use those words. It's an unclear question.

MR. STEIN: Okay. You can state your objection. If the doctor finds it unclear, then he can tell me.

MR. HAMAD: Fair enough. I did.

A. The report there are two said okay for transfer, eight and the tenth.

Q. Okay. Do you have an opinion as to why he did not say that the others were okay for transfer?

A. It's likely from the test that he has from CF10, no division for A and no division for ten and they got results from both mutations.

Q. And what was it about that, the others, to cause him not to indicate that they were okay for transfer?

MR. HAMAD: Objection to form.

99

MR. STEIN: Okay.

Q. Do you have an opinion as to why he did not label any of the others okay for transfer?

A. It looks like because of no amplification.

Q. What's the significance of there being no amplification?

A. No amplification means there is no information from that particular mutation.

Q. Okay. And so, therefore, those embryos which were numbered other than 8 and 10 would not be deemed okay for transfer. Is that correct?

MR. HAMAD: Objection to form.

That's totally misstating his testimony, but he can answer.

MR. STEIN: Okay.

A. The transfer of an embryo is finally determined by the patient, the couple, and physicians, because we -- again, I use my experience.

I think we had a case many years ago a patient wanted to transfer back, trisomy 21, which could lead to Down's syndrome and the physicians had to -- had a really difficult time to discuss. In the end it didn't transfer. I think a patient is the one that finally determines it, so I think a recommendation is here, but a transfer is determined by patient and the physicians.

100

Q. Well, when the patient makes a decision as to whether to transfer an embryo on this list that is not recommended as okay for transfer in the report of the laboratory as was here, what factors should the patient take into consideration in making that decision?

MR. HAMAD: Objection to form.

Clearly beyond the scope of this witness' --

MR. STEIN: Okay.

MR. HAMAD: -- expertise.

A. Well, I think it involve in the transfer. I am not involved in it.

Q. Okay. If the patient -- if 8 and 10 were not transferred, then say as in this case, 7 was transferred during invitro fertilization, was there a higher risk of misdiagnosis with No. 7 than there was with either 8 or 10?

A. I don't see that a particular higher risk. There is a risk -- you know -- ADO is a risk for any embryos, even clearly you will get both results and still have the risk of ADO.

Q. Okay. What is it in the laboratory analysis that makes 8 and 10 okay for transfer and 7 not indicated by Dr. Hughes to be okay for transfer?

MR. HAMAD: Objection.

That was exactly my point.

101

MR. STEIN: You have made -- you got an objection, just state it. Object and let's move on.

MR. HAMAD: Mischaracterizing his prior testimony.

MR. STEIN: All right. Fine.

A. Well, I think the report indicates what they have from the test and on the column, the last column on the right is the one, the recommendation, call it here, they put. I think the one no amplification they didn't have the results and they have to 8 and 10, they have the results and recommend it.

That's what I can see from the report.

Q. So, in fact, 7 has -- if they don't have amplification of the CF10 allele, then there is a greater risk that the embryo being transferred would be at risk of having an affected baby?

MR. HAMAD: Objection to form.

Q. Isn't that so?

MR. LEUCHTMAN: Argumentative.

MR. HAMAD: It was already asked and he answered it.

He can answer it again.

A. Well, there is one -- well, to whole PGD is trying to reduce the risk.

Q. Right.

102

A. When you have one allele, CF11, which is G542X mutation in the test that indicates it is a normal one. At least we get some information there and that information will reduce the risk, so, I think, in the PGD whenever you have, you got the results is reduce the risk, so the risk for No. 7 compared to without doing it is reduced.

Q. Okay. Reduced from 25 percent to what?

A. To -- well, the one that it doesn't have amplification, then it's 50. So 25 percent, because the one that you already have -- well, that means if there is no ADO, then it's normal, right for that particular mutation on that side is normal. Well, of course, you have to think about the ADO occurs. It could happen with whatever percentage we are discussing now whether its 70 percent or what we quote five to ten percent, so that's the risk.

Q. You quote five to ten percent?

A. Of each mutation of one single mutation as ADO.

Q. Right. And then the risk of misdiagnosis would be five to ten percent in your view when you don't have the amplification?

A. Well, the risk of ADO for that mutation and then you have 50 percent that are unknown, those both events occurs, so you have 50 percent times the five to ten

103

percent.

MR. HAMAD: What's that number?

Q. Which comes out to what?

A. Which comes out -- it should be 2.5 to five percent.

MR. HAMAD: That's for No. 7 we are talking about?

MR. LEUCHTMAN: Yes.

Q. 50 percent to 2.5 to five percent?

A. For ADO for X on 11 or G542. X is five to ten percent of ADO, because you already pick it up a normal allele, and you didn't see the T, which is five to ten percent. Exon ten, or delta F508, you didn't have information, so which means you have 50/50, right, so two events can happen, which the probability, then it's 50 times five or ten or five to ten.

Q. 50 times five to ten comes out to what?

A. Percent. Of a percent. Five to ten is allele drop out.

Now, on exon ten you don't have, you don't need to know allele drop out anymore, because you don't have it. If there is information there it is normal or it is affected, then you still have -- you have to calculate the ADO of that particular allele.

Q. It could be affected. It could be 100 percent?

104

MR. HAMAD: No.

A. That's why 50/50. It's a 50/50, because you don't know the information. You don't have the information.

Q. All right.

A. It's a 50/50.

Q. And so 50/50 on one side and five to ten percent on the other side?

A. On the other side.

Q. So it's greater -- if you have one side as 50/50, it's got to be greater than five to ten as the entire embryo, isn't it?

MR. HAMAD: Objection to form.

That's totally taking -- discounting the science. You have to have both together in order to fit the baby, you have to multiply it. That's what he has been doing.

Q. When you multiply 50/50 on one side and five to-ten on the other, don't you have a greater number than five to ten for the combined risk of both of them together?

MR. HAMAD: These are percentage points that you are talking about?

MR. STEIN: Yes.

MR. HAMAD: 50 percent times five to ten

105

percent what do you get?
We can pull out a calculator.
MR. LEUCHTMAN: .5 percent is .05.
MR. HAMAD: Okay.
Q. Okay.
MR. LEUCHTMAN: I get .05. That's just me.
MR. HAMAD: Doctor, so we can be clear, counsel is asking you the question:
For embryo No. 7, 50 percent in the one column times 25 -- times five to ten percent in the second column, gives you what percentage of allele drop out for embryo No. 7?
A. What percentage could be affected?
Allele drop out we already said, because for exon ten you don't have the information, so you don't calculate allele drop out.
Q. All right.
A. For X on 11 you have normal allele and there is a five to ten percent of risk of allele drop out, because it could be -- you may miss in five to ten percent of a chance, miss the mutant allele.
Q. The risk of misdiagnosis, you say, is the combination of the two, which is two and a half percent?
A. Two-and-a-half, or two to five.
Q. Okay. Now, in your report -- by the way, from

106

your awareness of Mark Hughes' history with PGD, did he invent PGD?
A. Well, I wouldn't say "invent," but he is a part of the pioneer, the first paper. He is a coauthor of the first paper in there, so I think he is the -- is one of the pioneers.
Q. Do you have any information as to why Mark Hughes left the National Institute of Health?
A. I don't have the detail. No, I don't know.
Q. Why he left Bayler University Medical Center?
A. That I don't know.
Q. Do you have -- have you heard anything about why he left Georgetown?
A. No, I don't know.
Q. Have you heard anything about why he left Wayne State University Medical Center?
A. No, I don't know.
Q. In your report when you referred to the literature regarding polar body --
A. Yes.
Q. -- the literature that you cite does not relate to the screening of human preimplantation embryos for chromosome abnormalities?
A. I am sorry.
Which page?

107

MR. LEUCHTMAN: Top of Page 3.
Q. Yes, you write, "As of today polar body biopsy for PGD is yet to be a mainstream approach. See a most recent debate article by Geraedts in Human Reproduction."
Do you recall citing that?
A. Yes.
Q. That article doesn't refer to compound heterozygous or single cell biopsy, does it?
A. That's -- yes, I agree with you. I think this is more of a general, yes.
Q. It refers to chromosome abnormalities, doesn't it, in that particular article?
A. Well, mainly refers to PGS or chromosome analysis, yes, but also -- well --
Q. Pardon me?
A. That's mainly --
Q. I am sorry.
It doesn't specifically refer to the situation we have here, does it?
A. No, it's not specific. It's a general.
Q. Okay. And you say in your report, and I quote -- the last paragraph, next to the last paragraph on Page 3, "In a published data collection ESHRE PGD consortium data collection, VII," and you cite that, but you go on

108

to say, and I quote, "based on the" -- I am going to withdraw that and ask you a different question.
"Based on the literature most misdiagnosis is due to intercourse or unprotected sex."
You make that statement. Is that correct?
A. Yes, in my report.
Q. Do you stand by that statement?
A. Well, this is based on the quote I also put in here, "Eighteen misdiagnosis have been reported, nine after PGD for PCR and nine after PGD or PGS using FISH. In all cases of misdiagnosis, unprotected sex during the PGD cycle could be responsible as any embryos generated in vivo would not be tested."
Q. All right.
Can you tell me whether or not there is any basis for concluding that the baby born to the Grossbaums was as a result of unprotected sex or intercourse during the critical period of IVF?
A. I think this is one of a possible reason. According to the literature I think one of the possible. I think it can be ADO. Could be contamination, or a host of different issues. I think it's not easy to pinpoint, but according to the literature, I think it looks like at least you cannot exclude that possibility.
Q. Doctor, isn't it true that the literature does

109

not say that most misdiagnosis is due to intercourse or unprotected sex. Isn't that a misstatement of the literature?

A. Well, the literature says it could be responsible in all cases of misdiagnosis.

Q. Does it say specifically that most misdiagnosis is due to intercourse or unprotected sex? It doesn't say that, does it?

A. It's different description.

Q. What?

A. It's a different description. I think it's -- that's -- you know -- again I quoted it here basically.

Q. And what you said there is an over statement, is it not, as to what the literature says?

A. Is it the best accurate, I don't know, but again I read in all cases misdiagnosis unprotected sex could be responsible. That's what I understand from the literature.

Q. And in order for it to be responsible, the patient would have to disregard the instructions of the -- the normal instructions given to a patient undergoing PGD IVF? Isn't that so?

A. I am sorry.

Could you repeat.

Q. In order for a couple to have -- to have a baby

110

as a result of unprotected sex, they would have to disregard the instructions given to them in the ordinary course of getting IVF and PGD, would they not?

A. That I don't know, what the patient take.

Q. Isn't it standard and normal for a patient or a couple undergoing PGD, to be told not to have unprotected sex during the period in which they are having PGD and IVF?

A. Yes.

Q. Okay. So if it's normal and standard for them to be told that for them to have unprotected sex, they would have to be disregarding their instructions, wouldn't they?

A. That I don't know for the patient. I cannot answer for the patient.

Q. And you don't have any basis for believing that they did not respect the advice given to them by the fertility clinic, do you?

A. I don't have.

MR. HAMAD: Objection to form.

Q. Now, in order to do linkage analysis on a patient or a couple, you would have to get a source for the DNA from either siblings or family members. Isn't that so?

A. Yes.

Q. Did you see any evidence in reviewing Dr. Hughes'

111

chart at Genesis Genetics that there was a request made of the Grossbaums to provide a DNA sample by way of blood or otherwise from any family members?

A. I see there is a note with a question mark. Dr. Hughes' note has a question mark of a parent. I think I noticed that one, blood possible from parents seems not -- that's only I notice. I don't see anything else that's read into this question, but this one.

Q. So you didn't see anything or indicate that they were asking for to give blood or that he didn't have it or that he wanted it and the Grossbaums were unresponsive. Isn't that so?

A. I don't see the details but it looks like a question mark "blood possible from parents."

That indicate to me he probably requested it, if that is possible from parents seems not. He definitely considered that.

Q. Okay. So that indicates to you that he made the request?

A. Yes, to me.

Q. Do you have an opinion as to the cause of the misdiagnosis in this case?

A. I think it's a complex and all the possibilities ADO or unprotected sex or others that may cause misdiagnosis.

112

Q. Are you able to give an opinion based on reasonable probability as to whether one or the other was more significant in causing this?

A. No, I cannot say one is more likely to the other.

Q. Okay. Do you see any evidence of contamination here?

A. No, but I have to add, even without -- well, from lab record there is no indication of it, but it doesn't really mean that it didn't happen, because contamination control is a difficult one even we include the blanks, but it does not exclude all the possibility of contamination.

Q. Now, Doctor, you have Dr. Hughes' report, which we have marked P-2 for identification in front of you.

And we have your report in front of us. Is that correct?

A. Right.

Q. Okay. Now, I would like you to look at the first paragraph under the listing, which starts "As I understand."

A. Uh-huh.

Q. Do you see the paragraph, four lines, is that right, four lines down, the first paragraph?

A. Yes.

Q. Okay. Your report -- this is Dr. Hughes' report.

113

Do you see four lines?
A. Four lines?
Q. Underneath the numbered paragraph, do you see the paragraph with four lines?
A. Uh-huh.
Q. Okay. And starting with "both Chaya Grossbaum," do you see where it says "both Chaya Grossbaum"?
A. Uh-huh.
Q. And look at your report, those four lines.
Do you see they are exactly the same?
MR. LEUCHTMAN: We have been through this, and he said, and this is an objection, that he authored the report without any conversations with Dr. Hughes, without any reference to anything Hughes has written.
MR. STEIN: I hear what you said.
Now can I ask him my questions.
MR. LEUCHTMAN: Obviously, I can't stop you from asking the questions.
MR. STEIN: Thank you.
Q. Do you see them, Doctor?
A. Yes.
Q. They are exactly the same, are they not?
A. Accept the one -- as I understand.
Q. Beginning with the words "both Chaya Grossbaum" and the rest of those four lines are exactly the same in

114

both reports, are they not?
MR. LEUCHTMAN: We will stipulate to that and we will stipulate the similarities are whatever they are.
Q. Do you see that?
A. Yes.
Q. Also there doesn't seem to be any of the idiosyncrasies in the language that were present in the earlier paragraph that you and I discussed. Isn't that true?
A. Sorry. Is that the list?
Q. Pardon me?
A. You refer to the list?
MR. LEUCHTMAN: You mean the entire report?
MR. STEIN: Can you not interfere with my questions, please.
MR. LEUCHTMAN: All right.
Objection.
The question is unclear, vague and ambiguous.
MR. STEIN: Okay.
Q. Do you understand my question?
MR. LEUCHTMAN: I am helping you to try to straighten it out.
A. Can you repeat it, please?

115

Q. Yes.
When we went over the earlier paragraph of your report that appeared at the bottom of Page 1, you and I went over it line by-line. Right?
A. Yes.
Q. And we found certain idiosyncrasies indicative of the fact that that was -- English being your second language, didn't have construction that you would leave without it being edited. You agree you indicated that?
A. Yes.
Q. But when I look at the paragraph that we are discussing now, which is the middle paragraph, if you will, on Page 1, where the four lines are identical, we don't see that -- any of that type of what I would call idiosyncrasies, do you see that, there is none of that in that paragraph?
A. Well, I don't recognize it, anything, yes.
Q. And you still say that that paragraph was written by you and not by anyone else, is that right, in your report?
A. Yes.
Q. Okay. Now turn to Page 2.
Doctor, in the Genesis Genetics report, which is the second full paragraph or the third paragraph in the middle, Dr. Hughes' report introduces it as "Dr. Kangpu

116

Xu has pointed out in his report," and then we see the words "an open question."
Do you see the words "an open question" in his report?
A. "An open," yes, I see.
Q. Okay. The rest of that paragraph is word for word, punctuation for punctuation, exactly the same as it appeared in your report, is it not?
A. I have to double check on it.
None of them appears to be fully effective.
Q. That's correct. That's not in Hughes' report?
A. So, I think, it's similar, but it's not.
Q. Everything up until the last line is exactly the same. Correct?
A. I see also there is a "since," I think it's not in my report.
MR. LEUCHTMAN: You know, again these reports are going to speak for themselves.
Since Hughes' report was after Kangpu's, as he has said, he is the person to be asking about this.
MR. HAMAD: I guess we will find out in 24 hours.
MR. STEIN: Yes.
MR. LEUCHTMAN: Okay. Perry Mason -- you know -- his report was first. I happen to know that

firsthand, but if you think that by some artful questioning you can get him to change what is the truth, we will sit here for another half an hour and you can point out all the commas and semicolons and all the rest of it.

MR. STEIN: When do we take your deposition, Mr. Leuchtman?

MR. LEUCHTMAN: Whenever you want, I suppose, if you can figure out a reason to take it.

MR. HAMAD: You guys realize he is taking all this down on the record.

Q. You also notice that we can turn to Page 3 of your report, we can see on Page 3 you begin a paragraph, "Because of the ever-present risk of ADO." Is that right?

A. Yes. I see it.

Q. That also appears -- the first two lines appear to be exactly the same in Hughes' report. Isn't that so?

A. That I don't know. I have to check his.

MR. LEUCHTMAN: We will take your word for it, Mr. Stein.

What's your question?

A. Where is his -- the --

Q. Well, try three paragraphs from the end of his

report on Page 3, do you see, "As alluded to above, because of the ever-present risk of ADO and other risk factors inherent in PGD, that CVS and amniocentesis are universally relied upon as a safety net in PGD," those are exactly the same words that appear in your report. Isn't that so, they're the same?

A. Yes, there is one sentence very similar.

Q. Okay. And then if we go to Page 3 in your report you have a paragraph that begins, "Because of so many variables," do you see that?

A. Yes, I see.

Q. And that's -- and those words appear in the rest of the paragraph exactly the same as is in Dr. Hughes' report. Isn't that so?

A. Yes. It looks like similar. I didn't go word-by-word.

Q. And then finally in the last paragraph, starting at, we see the words at the end of the first line, you say, "In summary I see a tragic case happened." And then we see the words and I quote, "not because of any negligence but unfortunately because of the complexity and the limitation of PGD technology and likely other confounding factors."

Do you see that, exactly the same words in Dr. Hughes' report. Do you see that?

A. I see the similarities, yes.

Q. And also did you notice that throughout those paragraphs the idiosyncrasies that were present in the first paragraph that you and I went over, do not appear present in any of the paragraphs that are similar between your report and Dr. Hughes' report. Do you see that?

A. I haven't checked that, definitely that paragraph.

Q. And you still maintain, Dr. Xu, that you did not have any input from Dr. Hughes in the construction of your report. Is that right?

A. Yes.

MR. STEIN: Give me a second and I will be finished. I am almost done, guys.

MR. HAMAD: I am just going to have one question.

MR. STEIN: Okay. Do you want to ask yours, and I will go over to see if I have anything else.

MR. LEUCHTMAN: Let's just finish it the way we are supposed to.

MR. STEIN: That isn't the way it worked when we took Dr. Cutting's dep, was it, Mr. Leuchtman? Was it?

MR. HAMAD: I don't remember that.

MR. LEUCHTMAN: I don't remember, Mr. Stein, in all honesty. I questioned -- no, I don't think I passed the witness.

MR. HAMAD: Actually, you know what --

MR. LEUCHTMAN: I had questions after he was done. It's not the same thing.

MR. STEIN: Yeah. Right.

I will take another minute if you guys want to wait.

(Whereupon, a discussion takes place off the record.)

CROSS-EXAMINATION BY MR. HAMAD:

Q. Doctor, if you can, can you tell me if there is a substantial difference in the risk associated with implanting embryo No. 7 versus embryo No. 8?

A. I don't see the substantial differences in the risk.

Q. Would it also be fair to say that embryo No. 7 is at least as good as embryo No. 8?

A. What do you mean "good"?

Q. Fair enough.

Would it also be fair to say that, embryo No. 7 is at least as risky as embryo No. 8?

A. Similar.

MR. HAMAD: Thank you.

No further questions.

REDIRECT-EXAMINATION BY MR. STEIN:

Q. You don't see any greater risk in No. 7 than 8, Doctor?

A. Similar, we calculated one side is unknown. The other side is, the lab test to pick up a normal allele, then the only risk is ADO.

Q. Okay.

A. For that particular limitation, ADO for that particular mutation, of course, we did not have, they did not have the information from delta F508 or Exon ten.

Q. And that doesn't mean that it's a greater risk than 8 or 10 with No. 7?

A. Well, that one does not have the information, of course, it has a risk.

Q. Does it have a greater risk between 7 -- does 7 have a greater risk of misdiagnosis than 8 or 10?

MR. HAMAD: Objection to form.

He just answered and told you that it doesn't, but he can say it many more times for you.

A. 10 or 8 already picked up from exon 11. It's a carrier, so itself compared to exon 11, 10 and 8 have a

higher risk, because it already has limitation from exon 11. 7 does not have or at least from the test did not detect the mutant allele.

MR. STEIN: Okay. Very good.

Thank you.

MR. LEUCHTMAN: Does that mean you are done?

MR. STEIN: I am done.

MR. HAMAD: No further questions.

MR. LEUCHTMAN: I don't have any questions.

MR. STEIN: I didn't think you did.

CERTIFICATE

I, PHILIP A. FISHMAN, a Certified Shorthand Reporter and Notary Public of the State of New Jersey do hereby certify that prior to the commencement of the examination DR. KANGPU XU was sworn by me to testify the truth, the whole truth and nothing but the truth.

I DO FURTHER CERTIFY that the foregoing is a true and accurate transcript of the testimony as taken stenographically by and before me at the time, place and on the date hereinbefore set forth, to the best of my ability.

I DO FURTHER CERTIFY that I am neither a relative nor employee nor attorney nor counsel of any of the parties to the action; and that I am neither a relative nor employee of such attorney or counsel; and that I am not financially interested in the action.

_____

PHILIP A. FISHMAN, CSR

Dated_____

C E R T I F I C A T E

I, PHILIP A. FISHMAN, a Certified Shorthand Reporter and Notary Public of the State of New Jersey do hereby certify that prior to the commencement of the examination DR. KANGPU XU was sworn by me to testify the truth, the whole truth and nothing but the truth.

I DO FURTHER CERTIFY that the foregoing is a true and accurate transcript of the testimony as taken stenographically by and before me at the time, place and on the date hereinbefore set forth, to the best of my ability.

I DO FURTHER CERTIFY that I am neither a relative nor employee nor attorney nor counsel of any of the parties to the action; and that I am neither a relative nor employee of such attorney or counsel; and that I am not financially interested in the action.

PHILIP A. FISHMAN, CSR

Dated 5/25/10

EXHIBIT H

IN THE UNITED STATES DISTRICT COURT

IN THE DISTRICT OF NEW JERSEY

----------/

CHAYA GROSSBAUM and MENCHEN GROSSBAUM, Her Spouse, Individually, and as Guardian ad litem of the Infant, ROSIE GROSSBAUM,

Plaintiffs,

-vs- Index No. 07-CV-359

GENESIS GENETICS INSTITUTE, LLC, OF THE STATE OF MICHIGAN, MARK R. HUGHES, M.D., NEW YORK UNIVERSITY SCHOOL OF MEDICINE, and NEW YORK UNIVERSITY HOSPITALS CENTER, both Corporations of the State of New York, ABC CORPORATIONS: 1-10 and John Doe,

Defendants.

_____/

PAGE 1 - 82

The Deposition of DR. MARK HUGHES,

Taken at 1380 Trowbridge Place,

Detroit, Michigan,

Commencing at 12:55 p.m.,

Page 2

Friday, May 14, 2010
Before Laura J. Steenbergh, CSR-3707, RPR, CRR, RMR

APPEARANCES:

NUSBAUM, STEIN, GOLDSTEIN
BRONSTEIN & KRON, P.A.
Attorneys for Plaintiffs
20 Commerce Blvd.
Succasunna, NJ 070876
BY: LEWIS STEIN, ESQ.
BY: LYNN HARRISON, PARALEGAL

TROWBRIDGE LAW FIRM
Attorneys for Defendants
Genesis Genetics Institute, LLC
And Mark R. Hughes, M.D.
1380 East Jefferson Avenue
Detroit, Michigan 48207
BY: STEPHEN LEUCHTMAN, ESQ.
BY: ALI ZAIDI, ESQ.

Page 3

APPEARANCES (Continued):

MARSHALL, DENNEHEY, WARNER
COLEMAN & GOGGIN
Attorneys for Defendants
New York University School of
Medicine and New York University
Hospitals Center
425 Eagle Rock Avenue, Suite 302
Roseland, New Jersey 07068
BY: JAY A. HAMAD, ESQ.

Page 4

INDEX TO EXAMINATIONS

INDEX TO EXHIBITS

Page 5

Detroit, Michigan
Friday, May 14, 2010
About 12:55 p.m.

DEPOSITION EXHIBITS P1 AND P2
WERE MARKED BY THE REPORTER
FOR IDENTIFICATION

MR. STEIN: Dr. Hughes, we're here today to take your deposition for the second time, since I have been in receipt of a letter dated March 2nd, 2010, addressed to Stephen F. Leuchtman, consisting of three pages, which we've marked for purposes of this deposition P1, and it would be Hughes 2, since we already had your deposition one time, and also a two-page bibliography, which I've marked P2 or had marked P2.

MR. LEUCHTMAN: It's not a bibliography.

MR. STEIN: That's my characterization. No, a biography. Did I say bibliography? I misspoke.

And which we've marked P2. And as a result of having received this letter and the advice that you plan to offer yourself as an expert witness in the event this matter goes to trial, we're here to take your deposition today on the basis of this recent submission.

DR. MARK HUGHES,

having first been duly sworn, was examined and testified on his oath as follows:

Page 6

EXAMINATION BY MR. STEIN:
Q. Now, let me show you the document, P1, and ask if you recognize that as the letter that you authored.
A. Well, I didn't write it, but I saw it.
Q. Okay. Is that your signature, Doctor?
A. Yep. Well, I didn't sign it with my hand, that's an electronic one, but yes.
Q. Okay. Well, if you didn't write it, could you tell me who wrote it?
THE WITNESS: Because you did it. Is this the letter when I was traveling?
MR. LEUCHTMAN: Yes.
THE WITNESS: Okay. So, yeah. So I'm trying to remember. I was out of town someplace, I can look up where, and Mr. Leuchtman asked me to put together a summary report for him, which I couldn't do, because I wasn't in -- I can't remember where I was, but I was out of town -- and he needed it like immediately, and I said why don't you put it together and I'll edit it.
So I was kind of impressed. You wrote this stuff, but I didn't. But I edited this electronically, and then I added my signature to it, and then I sent it back to you. Yeah.
MR. STEIN: Okay.
THE WITNESS: So but -- it's not exactly the way

Page 7

I would have written it, but you had some deadline or something you needed this by, so --
BY MR. STEIN:
Q. Okay. You are, in the phrase you, are turning to Mr. Leuchtman, who sits to your immediate left, and the you who you have referred to in your testimony is Mr. Leuchtman, is that correct?
A. That's --
THE WITNESS: You wrote this, you put this together. Because you sent it to me as an e-mail, Mr. Leuchtman, right?
MR. LEUCHTMAN: Yes.
THE WITNESS: Okay. Because I didn't write this. I didn't actually write this.
MR. HAMAD: Yes, to which -- there's two questions there. Yes, you wrote it, or yes, you sent it as an e-mail?
BY MR. STEIN:
Q. Well, the answer may have two parts to it but my question to you is simply --
MR. LEUCHTMAN: I sent it to him.
MR. HAMAD: Exactly.
MR. STEIN: Listen. If you would be kind enough to listen to my question.

Page 8

BY MR. STEIN:
Q. You have given testimony under oath which this young lady to my left and your right is recording, as a shorthand reporter, verbatim.
A. Yes.
Q. And in connection with that recording you have used the phrase you in your answer, and turned to your left and looked at Mr. Leuchtman, is that correct?
A. That's correct.
MR. LEUCHTMAN: Well, some would call you a word and not a phrase, but whatever.
THE WITNESS: That is correct.
BY MR. STEIN:
Q. And so my simple question was, when in the transcript we read the word you wrote this, in that phrase, and you look at Mr. Leuchtman, you are, in effect, referring to Mr. Leuchtman as the person who wrote this, is that correct?
A. He wrote this document, which I edited electronically, signed, and sent back to him, yes.
Q. And how did you obtain -- you obtained electronically this three-page letter, as it now appears, before editing, and then you edited it on your computer --
A. Um-hum (affirmatively).
Q. -- and electronically sent it back to him, is that right?

Page 9

A. That's correct.
Q. And then is it your understanding that that's the last you saw of the letter before it was transmitted to me?
A. That was the last I saw the letter until now.
Q. Okay. So I take it you haven't read this letter in preparation for today's testimony, is that correct?
A. No, no.
Q. That's not correct, or is correct?
A. I haven't read this letter in preparation for this testimony.
Q. Okay. Now, can you tell me where Genesis Genetics is located vis-à-vis the location of this office that we're now in?
A. It's about 10 miles, 12 miles east.
Q. Okay. And it appears to have been provided to me in the form we've marked P1/Hughes 2 on the stationery of Genesis Genetics.
A. Um-hum (affirmatively). Old stationery, by the way.
Q. Pardon me?
A. It's older stationery, but yes.
Q. Do you have any understanding as to how Mr. Leuchtman obtained the Genesis Genetics stationery?
A. No. I put it on the stationery. So he sent it to me as a document. I can find it in my e-mail box. He sent it to me as a document, I edited it, put it on the

Page 10

stationery electronically, and sent it back to him. Because we don't have stationery printed. We use the electronic version in the computer.
Q. So that letterhead is a product of your electronic capacities in your computer, is that it?
A. Um-hum (affirmatively).
Q. Now, this computer, is that a laptop that you take with you?
A. Um-hum (affirmatively).
Q. Okay. Now, I take it that in some way you got this request to provide this report from Mr. Leuchtman at the last minute or some way where you had to effectuate this?
A. I don't remember the details, but -- I don't remember the details. What I remember is he was -- he said I've got to have a letter from you saying blankity-blank, whatever it was. And I said, well, how detailed does it have to be, and he said fairly detailed. And I said, well, I don't have any of those records with me, when do you need it by, and I wasn't going to be back. So he composed the letter.
Q. Okay. Can I assume --
THE WITNESS: I assume you composed the letter, or an assistant of yours, or somebody composed the letter. I actually was kind of impressed with it, because I agreed with most of it, but I took some things

Page 11

out. I can't remember what, but I could go compare.
BY MR. STEIN:
Q. You can go compare because you have the data in your computer as to the form that you received the letter from Mr. Leuchtman?
A. Right. I should have that, yeah.
Q. And that's a --
MR. LEUCHTMAN: I think we've gone about far enough into attorney-client privilege.
MR. STEIN: Well --
MR. LEUCHTMAN: I'm not sure where you're going with this, Mr. Stein, but I'm going to instruct Dr. Hughes not to answer any further questions about the give and take between he and I in the generation of this report. You have most of the answers you're seeking anyway.
MR. STEIN: Well, I have his comment with respect to that objection. Are you instructing him not to answer any further questions on this subject invoking the attorney-client privilege, Mr. Leuchtman? Let me get that clear.
MR. HAMAD: What subject are you --
MR. LEUCHTMAN: Well, it's also work product. Yeah. You mean how the report came to be?
MR. STEIN: That's all we have discussed in this

Page 12

deposition to this moment, so how anybody could have any further need for clarification as to what I'm talking about and the subject matter of our discussion in which you're invoking the privilege is beyond me. It's clear you have just interrupted the questioning by stating this has gone as far as you think it appropriate, considering the effect or implications of the attorney-client privilege.
MR. LEUCHTMAN: Well, and work product. The issue is does it reflect his opinions. You haven't asked that, and I hope at some point you do, i.e., in the next question, and then maybe we can move on to the substance of your inquiry in this deposition.
MR. STEIN: Well, what you would like and what I intend to do have no relationship in reality, Mr. Leuchtman, since I am here to decide what I think is appropriate questioning of a deposition on a report I received that purported to be a report of an expert. Now, I intend to continue asking questions on how that report was created. If you are going to instruct your client not to answer any further questions , I will address that issue. If you're not, I'm going to continue to pursue the details of the production of that report. Now, you'll have to advise me as to what the nature of your further action will be regarding the objection.

Page 13

MR. LEUCHTMAN: Well, I'm not sure at this point. It depends on the next question you ask, I guess.
MR. STEIN: Okay.
MR. LEUCHTMAN: However, he has testified that he got that from me, that he edited it, and then he sent it out, and that it is his report.
MR. STEIN: I know what the testimony is, I've listened to it for the last 10 minutes. Now --
MR. LEUCHTMAN: Yes, and often repeatedly. I mean, let's --
MR. STEIN: Now, are we going to continue with my questioning, or are you going to interpose an instruction to your client raising privilege on either of the two grounds that you've stated that he not answer any further questions on that issue?
MR. LEUCHTMAN: Ask your next question, and we'll just see where we go from there. But I hope it's a new one, since basically you've asked three questions in slightly various forms over and over again.
BY MR. STEIN:
Q. Dr. Hughes.
A. Yeah.
Q. Do I understand that you still possess the computer on which you communicated with Mr. Leuchtman regarding the creation of the report which I've marked P1/Hughes 2?

Page 14

MR. LEUCHTMAN: I'm going to object to the form of the question. He has no idea what you understand, but subject to that objection, you can go ahead and answer the question.

Unless you want to rephrase it so that it makes sense.

THE WITNESS: I am fairly certain -- until you look you never know for sure -- but I'm fairly certain that I would have the e-mail that he sent me with the text here in it that I then sent back to him on letterhead. I should still have that in the computer, yes.

BY MR. STEIN:

Q. And that's a laptop computer?

A. Yes.

Q. What's the nature of the computer? Can you identify it for me, the make and model of the computer?

A. It's a Dell. I forget. And the signatures, I have them in a file and I just drag them over and put them on documents when I'm traveling.

Q. Okay. Now, do you have a file on this case here with you today?

A. No. Well, the only thing I have is this -- is the -- is this. I have my notes from the laboratory.

Q. Okay. Do you have a file within your computer relative

Page 15

to this case?

A. I have a folder that contains some correspondence and notes, yes, about the case.

Q. And that's where you would, I expect, find the e-mail communication that you're now talking about?

A. No. It would still be in the e-mail in and out box, I think. But I have to go look.

Q. Are you in a position to look now, here?

A. No, I don't have it here.

Q. Okay. Can I assume that the e-mail communication between you and Mr. Leuchtman regarding the creation of this report was on or about March 2nd or a few days before that?

A. I frankly have no idea. I don't remember when this was. I remember seeing this, I remember working on it, but I frankly don't remember when. You could have told me it was January and I'd have said okay. I mean, I don't know.

Q. Okay. Well, it bears the date of March 2nd, does it not?

A. Yes, it does.

Q. Do you know where you were traveling on March 2nd?

A. Nope. But I could look it up.

Q. And what do you have to do to look it up?

A. Go onto my computer and look on my calendar.

Q. Okay. And that, again, is not here today, is that

Page 16

correct?

A. No.

Q. Okay. Now, at the time that you had this exchange with Mr. Leuchtman regarding the content of this report, had you been aware that Dr. Xu had prepared an expert report in this case?

A. Dr. Xu?

MR. LEUCHTMAN: Kangpu.

THE WITNESS: Oh, Kangpu Xu. Okay. No. As a matter of fact, I know nothing about what -- in fact, I found out today that Kangpu gave his deposition. I didn't even know that. I was in Europe all last week. So I didn't know -- I haven't talked to him since -- the last time I saw Kangpu was in Atlanta at the ASRM meeting last October.

BY MR. STEIN:

Q. Okay. And at that time you talked to him?

A. Um-hum (affirmatively).

Q. And did you mention to him at that time the fact that you were being sued for a misdiagnosis by one of your patients?

A. No.

Q. Had you ever talked to him about this case?

A. Never.

Q. Was it your idea that -- is his proper name referred to

Page 17

as Xu is his last name, or is it a combined --

A. Well, no. His first name is Kangpu, and I've always pronounced his last name Xu, but that might not be correct. But that's what I've always said.

Q. We'll refer to him as Dr. Xu.

A. Okay. That's probably more correct.

Q. Which I think he acknowledged to be the preferred pronunciation.

A. Okay. Don't tell him I didn't know how to --

Q. And was it you who suggested that Dr. Xu be consulted to be an expert on your behalf in this case?

A. I gave my counsel a list of names to choose from, of people who I thought might be good, and he was on that list.

Q. And you allowed your counsel to choose?

MR. LEUCHTMAN: Well, objection. You don't have to answer that. How is this -- it's strategy with an expert, and it's attorney-client privilege and work product. He's told you he gave me a list.

MR. STEIN: Mr. Leuchtman, I respectfully suggest that you have, to the extent that you have been involved, as now described, in the preparation and submission of this report, have in all likelihood made yourself a fact witness in this case, so you can be guided accordingly as to how you want to conduct yourself, but that's my view

Page 18

of the law and the legal rights that the people may have here. But --

MR. HAMAD: Do you want to take a couple minutes just for a second?

(A recess was taken).

MR. STEIN: Are you gentlemen ready to resume this deposition?

MR. LEUCHTMAN: Well, we are. However, subject to my motion to strike all the questions about how this report came into existence on a basis of attorney-client privilege, and I'm going to instruct Dr. Hughes not to answer any further questions about how the report came into existence. He is here in his capacity as an expert, however, he's still my client, and you are getting into attorney-client privilege, and we will have no more of it.

MR. STEIN: Well, I intend to ask the questions so that we have a record, and you can simply object and say the words attorney-client privilege and we go from there. Okay?

MR. LEUCHTMAN: If that is your prerogative, yes, sir.

BY MR. STEIN:

Q. Okay. Dr. Hughes, you've indicated that you received an e-mail draft of a report which you edited while you were

Page 19

out of the country on or about March 2nd, 2010, is that correct?

MR. LEUCHTMAN: Objection, attorney-client privilege. Don't answer the question.

BY MR. STEIN:

Q. Okay. And you edited the -- I think you said you edited the e-mail that you received, is that correct?

MR. LEUCHTMAN: Objection, attorney-client privilege. Don't answer the question.

And by the way, we're not conceding that these questions are accurate as stated or an accurate reflection of Dr. Hughes' testimony, which will be struck anyway.

MR. STEIN: Okay.

BY MR. STEIN:

Q. I understood you did say you were traveling. Now, I may have assumed that the travel was out of the country, so I'd like to know whether you can recall where you were traveling at that time.

MR. LEUCHTMAN: Objection, for the same reasons.

BY MR. STEIN:

Q. Now, you indicated you edited the e-mail that you received from Mr. Leuchtman that is the form of report that ultimately I received. Can you describe for me whether or not you rewrote any of the entire paragraphs

Page 20

in connection with the e-mail you received?

MR. LEUCHTMAN: Same objection, same instruction.

BY MR. STEIN:

Q. Can you tell me whether you recall any of the portions of that report -- withdraw that question.

Attached to the report is a two-page document which we've marked P2. Do you see it there?

A. Yep.

Q. Now, that has been offered, it's been marked P2/Hughes 2, and it's been offered what appears to be in satisfaction of a customary requirement that a CV be provided with respect to any expert report that is submitted. Do you recognize P2/Hughes 2?

A. It's old, but -- I do not know where this exactly came from.

MR. LEUCHTMAN: Well, you weren't asked that, just whether you recognize it.

THE WITNESS: Well it's my picture, and it's -- you know.

BY MR. STEIN:

Q. When you say it's old, can you tell me what you mean by old?

A. Oh, it's over five years old, I think. Maybe eight.

Q. Are you the author of the content of the document which we've marked P2/Hughes 2?

Page 21

A. No. This was written by somebody who was going to introduce me at some function. And so I recognize parts of it, so it's just been -- it looks like it's been cut and pasted. Yeah. I give lots of lectures, and people have something that they hand out, and this is the kind of thing that they do.

Q. Well, do you provide the people who hand this kind of thing out with the information to be included in --

A. Sometimes. And sometimes they just go on the Internet and get it, put it together.

Q. So this particular document, as it now appears, P2/Hughes 2, have you ever seen it before in its present form?

A. I've seen versions of this, so I don't know for a fact that it's exactly this one, but I've seen versions of this. Usually I -- I was reading the bottom, usually it will say something like the such and such society is pleased to have -- something. And this is something that the person who introduces me reads usually or something like that.

Q. Okay. I understand what it usually is, but I'm asking you if you have ever seen this particular one before.

A. I couldn't say. But I've seen versions of this, but I don't know if I've seen this one.

Q. Okay. And P2/Hughes 2 consists of two pages. I'd like to direct your attention to the second page of P2/Hughes

Page 22

2, and ask you if you've ever seen that page before.
A. No. But I've seen these comments before.
Q. And what do you mean by you've seen comments before?
A. Well, like some of these sentences I've seen in many places. Like I completed an MD at Baylor, and did this and that, and a collaboration with the Hammersmith Hospital in London, that's kind of a canned paragraph that I've seen many places. And the part about Science Magazine I've seen. I think usually what happens is that somebody writes this, puts it on the Internet, and then other people find it, and then they just adjust it for their own use.
Q. Now, while I look at P2/Hughes 2 -- you don't have a copy then for your use, is that correct?
A. No, I don't have one.
MR. LEUCHTMAN: (Indicating).
THE WITNESS: Okay. I do.
BY MR. STEIN:
Q. Okay. Now, in the second paragraph of P2/Hughes 2, there appears the words, Dr. Hughes moved to Michigan to take a position as professor and director of molecular medicine and genetics, professor of OB-GYN, and professor of pathology, but it does not identify the institution which you took that position. Did you notice that, Doctor?
A. No, I didn't.

Page 23

Q. Well, if you look at it now, you'll see that it does not mention the name of the institution, correct?
A. Okay.
Q. Could you tell us what institution you took that position?
A. Wayne State University.
Q. And a particular division of Wayne State University was it, Doctor?
A. Well, it was the College of Medicine.
Q. And were you in a particular department?
A. Well, I was in multiple departments.
Q. Okay. Well, did you have emphasis in one department more than another?
A. Yes. Genetics.
Q. And did you have a superior in the department of genetics at that time?
A. The department was in transition, but yes, there was a Dr. Grunberger, who was my chairman until he stepped down.
Q. And were you still there when he stepped down?
A. Yes.
Q. Okay. And did the medical school have a head, like a president or a dean? How did the hierarchy at that school exist at that time?
A. Well, there's the university president that is over the

Page 24

colleges. My laboratories were over in the College of Sciences building, but my appointments were in the College of Medicine.
Q. And who was the president at that time?
A. It changed when I was arriving, but Irving Reid.
Q. Was he there when you left?
A. Yes.
Q. And were you asked to leave?
A. No.
Q. Was there any issues regarding your continued stay there at the time you left?
A. Yes.
Q. And what were those issues?
A. The medical school had a -- made a decision that they didn't want to practice medicine. Unlike some medical schools that have a hospital, Wayne State University doesn't have a hospital. So they provide education and put medical students and residents and fellows into hospitals in the area. And the decision was made that doing embryo testing was a clinical activity that needed to happen in a hospital, not actually in my research laboratory. Because the field was moving to becoming more of a service and less of a research process. So we had discussions about forming a non-profit organization that would be outside of the university in which this

Page 25

would occur. And we actually did that, we formed a non-profit company. But the university bureaucracy was at a pace at which it was more and more difficult than I -- they wanted me to stop doing this. And there were patients that were asking for it, and so I said, well, I'm going to resign and go work in the nonprofit.
Q. When you say you set up the nonprofit, was that with the consent of the administration at the time it was set up?
A. Yeah. All the discussions were with the vice-president of research.
Q. And who was that?
A. George Dambach.
Q. Can you spell the last name, please?
A. D A M B A C H.
Q. Okay. And was he there at the time you left?
A. I think so, yeah.
No, I think he just left. I'm not -- I don't remember. Right around that time he left.
Q. Okay. Now, you had previously been at the National Institute of Health, is that right?
A. Yes.
Q. And when you left the National Institute of Health, were there any issues between you and the National Institute of Health?
MR. LEUCHTMAN: Objection, vague.

Page 26

MR. STEIN: Okay.
MR. LEUCHTMAN: I'm not telling him not to answer.
THE WITNESS: Oh. I'm now gun shy. Whenever you talk I don't know what to say.
Yes, there was. I was -- can I extrapolate? I was recruited to the NIH and Georgetown University because of my research in embryo science, and did significant amounts of work there, and gave major lectures at the NIH and at Georgetown, and taught on the subject, and was quite publicly known. Then there was a change in the administration of Washington. The republicans took the house for the first time in decades, and Newt Gingrich was the speaker of the house, and the philosophy of doing anything whatsoever with an embryo anywhere near the NIH became of a concern because we were all very actively trying to double the NIH budget at the time. So we were all busy lobbying to get more money for biomedical research. And so suddenly I became a liability in that quest.
BY MR. STEIN:
Q. And so they asked you to leave?
A. Yes. Well, they said I could stay, but I couldn't work on this. And then the good Jesuits were now in the public eye, and they became concerned because it was

Page 27

obvious what was going on, and so --
Q. Did you continue to work with embryos after it became government policy not to allow that type of research at the NIH?
A. I don't know anything about the policies of when it was or when it wasn't. What I know is that when the decision was made that we shouldn't do this at the NIH, or have a faculty member -- or, not a faculty member -- a staff member of the NIH doing it even across the street at the Samaritan Hospital because of the political issues involved, I was asked to resign.
Q. Were you using NIH offices to conduct the research that you were doing contrary to government policy?
A. No. I was using the offices at Georgetown.
Q. Okay. Now, turning to your deposition, Exhibit P1, which is your report, three-page report, in the paragraph before the bottom of the first page that begins, I spoke with the Grossbaums and conducted the interview that you have described in your report, I take it that that conversation lasted for some time?
A. They usually last a good hour, sometimes longer.
Q. Okay. Now, that is, obviously, direct contact between you and what would become your patient when they sent the laboratory materials from NYU, is that correct?
A. Not exactly.

Page 28

Q. Okay. And I take it that you suggested that is not a contact with a patient in the sense that a doctor has contact with patients, is that correct?
A. In general laboratories never talk to patients. They do the test that was ordered, they write a report, they send it to the person who ordered the test, and that's the extent of it. In the field of PGD, the few of us that do this feel that it's more important to communicate beforehand with the patient about the risks and benefits of the procedure. Because sometimes the doctors at the clinics don't necessarily know the nuances of the latest. They're IVF experts, not genetic experts. So from a perspective of an informed consent, we take and go the extra mile and spend time with them, a significant amount of time with them, explaining to them the steps involved.
Q. Now, have you ever encountered the issue with regard to practicing medicine in the State of Michigan under its rules and regulations for the medical profession?
MR. LEUCHTMAN: Encountered what issue? Object to the form of the question as vague and ambiguous.
MR. STEIN: I'll rephrase it.
BY MR. STEIN:
Q. Has the issue ever been raised with the regulatory authorities in Michigan who regulate the practice of medicine as to whether or not the contacts that you have

Page 29

with the patient constitutes practicing medicine?
A. I don't have a license in Michigan to practice medicine. I don't practice medicine. I happen to have an MD, but what I do is science, it's my PhD. I don't practice medicine.
Q. And you don't consider the providing informed consent to the patient who's going to be a prospective submitter of materials for laboratory analysis to be practicing medicine, is that right?
A. Not even remotely. It's more like a genetic counselor. That's why we don't talk to the patient during or after the case.
Q. Okay. Now, when you said -- and you have a copy of your letter in front of you?
A. Yeah.
Q. And you say in that paragraph that -- you explained, to quote you, I explained the technology involved isn't perfect and pushes medical diagnostic technology to its absolute limit.
Can you tell me what you mean by that?
A. Yes. Unlike testing that's done in almost any other field of medicine, we're studying the smallest unit of life, one cell. And we're studying it for the smallest unit of inheritance, one gene. And we're studying it for the smallest possible part of a gene, changes of a single

Page 30

letter, a single molecule. And 100 years from now the technology can't be smaller than that. And we have to do it overnight. So the point that we make to the patients, which is the reason why not only does the laboratory have an informed consent, but the clinic does, is to reiterate recovery and over that this is the limits of medical diagnostic testing. In fact, it's been that way for 20 years.

Q. Well, I think you've indicated in Hughes I that at the time of that deposition you had done over a thousand cases, is that right?

A. Oh, yeah.

Q. And you're aware of the clinic that Dr. Xu -- that is the laboratory that Dr. Xu is connected with, the Center For Reproductive Medicine and Infertility in New York, are you not?

A. Um-hum (affirmatively). I am.

Q. And are you aware that that laboratory and that clinic has done over 3,000 cases of PGD?

A. Well, there's a nomenclature issue here.

Q. Okay. And what is that?

A. Cornell does a technique called PGS, Preimplantation Genetic Screening. This is a technique that was in vogue in the mid-2000's, in which you look at chromosomes. But they send almost all of their single-gene tests to us.

Page 31

They do sickle cell anemia and cystic fibrosis, and there's a few tests that they do there inhouse, but most of the cases they send to us. So it's counting apples and oranges, because they're different techniques. One technique is looking at genes, and one technique is counting chromosomes to look for abnormal number of chromosomes.

Q. So they don't do single-cell analysis for cystic fibrosis there?

A. They do. They do cystic fibrosis, and sickle cell anemia, and I'm not sure what other ones, but virtually all of their cases that are not those few they do they send to us. So I can assure you there's no way they've done 3,000 single-gene cases of PGD. Not even close.

Q. How about 1300 cases of PGD?

A. We need to define the difference in order for the numbers to be accurate. In order for me to answer the question I need to know what we're talking about. If we're talking about embryo testing of a sample, whatever the sample is, for a gene defect, as opposed to chromosome numbers. If you lump the two together, the numbers are huge. Because this technology of FISH was widely used by many groups, including Cornell for a while. If you talk about single-gene testing, like for cystic fibrosis, I don't know how many they've done, but not anywheres near 1300,

Page 32

I'm sure.

Q. No, cystic fibrosis they've only indicated they've done 70.

A. Okay.

Q. But are they still sending single-cell analysis to you?

A. Um-hum (affirmatively).

Q. And this has been continuing all during that period of time?

A. Yes. In fact, last week or the week before we received a sample from them.

Q. Okay. Do you interact with Dr. Xu at Cornell in connection with the referrals?

A. No.

Q. Who do you interact with there?

A. I don't, but the team interacts with a woman -- whose name I'm blanking out. But there's a woman there who does it all, who actually, I think, runs the lab, I think. I'm not sure. But we interact with the nurses, and with the embryologists, because we're the laboratory in which they are interacting with if they're sending the sample out.

Q. And do you interact with the doctor or physician who's involved with the IVF there?

A. Almost never. Unless they call because they have a question.

Page 33

Q. And when they call --

A. Are you talking about Cornell, or NYU now?

Q. I'm talking about Cornell.

A. It's the same for both. I just want to make sure we're on the right institution.

Q. Okay. Now, you also indicate in that letter that the technology can fail. Can you tell me in what manner the technology can fail?

A. Oh, many ways. So the cell that is biopsied may not represent the rest of the embryo. The cell that's biopsied may not have a nucleus. The cell that's biopsied may not be properly transferred to the tube to be sent, it gets stuck on the wall or some other place. The amplification technique that is used to make multiple copies of that DNA can fail, or partially fail, or fail because one or other of the chromosomes aren't there, or there's too many. You can have failures because of DNA contamination. You can have failures because of allele dropout.

Q. And these various ways in which --

A. And more. There's more, but --

Q. Okay. Is there an explanation as to why a laboratory like the one at Cornell would have -- and, by the way, failures can be found before the report is issued, it could be an in-house identification of the failure, is

Page 34

that correct? Or are you talking about failures resulting from misdiagnosis?
A. I'm talking about a failure -- it depends on how you're defining failure. I'm trying to answer the global question.
Q. Well, I'm trying to understand how you used the term in your report that the technology can fail. Are you talking about misdiagnosis there?
A. One of the things.
Q. What else were you talking about when you talked about the technology can fail in that report that you submitted?
A. So that you either can -- there can be an error, a laboratory error or some or error, or there can be no answer at all in the sample.
Q. Okay. So in the context of the communication that you had with the Grossbaums, were you talking about both a failure in terms of the sample and in respect to misdiagnosis?
A. I'm talking about failure in the global sense.
Q. Now, with respect to the Grossbaums, you indicated that you had to have a custom design for their analysis of their cells sent from the embryos, is that correct?
A. Yes.
Q. And that custom design is that described as their asset?

Page 35

A. Yes.
MR. STEIN: Would your mark these P3 and P4?
DEPOSITION EXHIBITS P3 AND P4
WERE MARKED BY THE REPORTER
FOR IDENTIFICATION
BY MR. STEIN:
Q. Do you recognize P3 and P4 as the designs provided by you to me as being the assays design for the Grossbaums?
A. This looks like the designs from our -- they look like the same. Yep, this looks like it's right, yes.
Q. All right. And are these created in your laboratory specifically for the studies to be done of the Grossbaums' cells that are submitted by NYU for your analysis?
A. Well, we have multiple different assays that we need to try to see which is going to work for them. This is the one that was selected.
Q. Okay. And what's the process by which you try these, I think, as you say, multiple designs that would work?
A. We obtain DNA from the critical family members, and we sequence the DNA in the area of which the mutation has been reported to be. We always want to confirm the mutation from the outside laboratory that found it. And then we run a battery of marker pairs against their DNA in two picograms amount of DNA, basically equivalent to

Page 36

one cell, in order to see which is going to work the best. And in this case it was complicated because we have two different mutations, the man and the woman have two different ones. So we wanted to be able to see them both at the same time, so that would be a multiplex analysis, which is a bit more complicated. So we test those ahead of time.
Q. And this is from the couple who was submitting the cells for analysis, is that correct?
A. That's correct.
Q. And these were the designs that were selected, is that right?
A. Yeah. I would say so, yep. I mean, if I sent them to you or had them sent to you, then that's right.
Q. Okay. And now, again, as you just indicated, you would not have taken their case if they did not agree to do the CVS and the -- or, alternatively, an amniocentesis?
A. That's correct.
Q. But you don't -- you did not in those words say that to them, is that true?
A. I don't remember exactly what I said. I'd have to go back to the notes.
Q. Okay.
A. But to that effect that it's a requirement of our process and if they are unwilling to do that, then we can send

Page 37

them someplace else.
Q. And where do you send them?
A. Well, probably RGI, but I don't know.
Q. Okay. Well, when you say -- I think you indicated in your report that you send them someplace else, didn't you?
A. It depends on -- in 2004 I don't remember exactly where we were sending patients, but it would be different places for different mutations, but in general there's really only a couple of places that do this. So we would refer the patient probably to Genetics and IVF in Virginia, or to RGI in Chicago.
Q. And those laboratories, as far as you know, do not have that as a firm condition for them to do an analysis, is that correct?
A. I don't know what their process is, but they are other laboratories that can offer this, they're quite good, and so they can talk to the genetic counselors there to identify what would be possible for them.
Q. Well, Doctor, I take it you would not be referring a potential couple for analysis at Genesis Genetics to another laboratory if you weren't aware that that laboratory did not have the requirements that you have that they agree --
A. Well, first of all --

Page 38

Q. -- to CVS or amnio in advance, is that right?
A. No. No. So first of all, I don't do any referring, because the patient isn't mine. The patient belongs to the clinic and the doctor who's taking care of them. So we would tell that doctor -- as far as I would go is I would tell the patient that we wouldn't be able to help them, that there may be other laboratories who would, that we will communicate this back to their physician, and then they can decide where to go, but we can't help them.
Q. So is it your testimony that you were not aware whether or not the other laboratories that you mentioned, RGI or the laboratory in Virginia, would do a PGD study on a couple that did not agree to do amnio or CVS, is that your testimony?
A. I don't know what their policy would be in a given case, depending on the rarity of the mutation, the type of mutation, the number of samples that would be available. I don't know what their policies would be.
Q. We're talking strictly about a policy that you indicated exists at Genesis Genetics at that time, and I take it to the present.
A. That's correct.
Q. That you will not have taken a case if the couple do not agree to undertake CVS or amnio following the IVF

Page 39

procedure, is that correct?
A. That's correct.
Q. That's your policy?
A. That's our policy.
Q. And you were not aware, either at the time that you saw the Grossbaums or even today, as to whether or not the other laboratories that do the kind of PGD studies that you do would do those studies without a commitment for the people to undertake amnio or CVS, is that correct?
A. I do not -- I can't comment on the policies of the other places, and I'm not aware of it.
Q. Okay. And is it your testimony that you yourself would not have been referring anyone to these laboratories, it would have to be the doctor that --
A. Right. Because the patient, if I was to tell NYU that I've referred their patient to another laboratory, they'd have a fit, and rightfully so.
Q. Okay. So then you've never referred then to organizations who did not require conventional prenatal follow-up, testing, amnio or CVS, is that right?
A. I don't refer patients to anywhere. I tell patients that -- and there's about three or four a month -- I tell them we're unable to help you, and I explain why. And I say we will talk with your doctors and there are other laboratories that might be able to help you.

Page 40

Q. Okay. And this was the practice at the time that the Grossbaums had their studies?
A. Yes.
Q. And this is a status that you've always known to be the case, is that right? I'll withdraw that question. That's a vague question.
Well, can you tell me then, Doctor, why at the top of page two of your report, P1, I read the following statement, I have had people over the years voice objection to amnio or CVS, and when this has happened I have referred them to organizations who did not require conventional prenatal follow-up testing with amnio or CVS.
Can you tell me how you could write that in a report and yet testify the way you have here today?
A. I'm not specifically referring the patient to another organization. That's incorrectly stated. I've never referred a patient to another center. I give them options through their doctor.
Q. Okay. Now, you've also indicated in your report that you discuss the risk of misdiagnosis, is that correct?
A. Yes.
Q. And -- give me a second.
All right. Doctor, I believe you indicated in your prior deposition that the risk of misdiagnosis was

Page 41

between three and five percent, is that correct?
A. That's the risk that's quoted around the world in other PGD programs, and in general the genetic counselors quote that number. In our group it isn't that high, but that's the number that's been sort of announced by --
Q. Okay. Can you tell me, when you say that's announced by other groups and around the world, where are these announcements made? What specifically are you referring to?
A. So at scientific meetings people stand up and talk about the error rates that they see.
Q. And you have a specific recollection of people standing -- of particular people standing up?
A. Sure.
Q. Okay. What group or what person in these meetings do you recall standing up and they have an error rate of three to five percent?
A. They don't necessarily say that they have an error rate. They quote that as the rate in the field.
Q. Okay.
A. And I've always thought that was high.
Q. Okay. In other words, individuals have stated at meetings, who are attending the meetings and are working in the field, that the error rate in the field in general is three to five percent, is that correct?

Page 42

A. I've heard that many times.
Q. Okay. And has that error rate changed over time?
A. Actually the quoted numbers from just last week at the international meetings were still three to five percent.
Q. Okay. So someone got up and quoted three to five percent at the meeting last week?
A. I heard it discussed, yes.
Q. Okay. And who did you hear it discussed from? Who said it?
A. I'd have to go look.
Q. And where would you look?
A. I'd look at the minutes of the meeting that we just had.
Q. And those minutes are circulated?
A. No. They're notes that I would have taken. Or they might be in the abstract. We can look.
Q. And is the abstract circulated for everybody who's in attendance at the meeting?
A. Yes.
Q. And what was the nature of the meeting, what was the group that met?
A. The PGD International Society.
Q. And where was the meeting?
A. France.
Q. And was Dr. Xu there?
A. No.

Page 43

Q. And your rate is less than one-half of one percent, is it not?
A. No. Our rate runs between one and two, depending on the year.
Q. So each year you have one to two percent misdiagnosis?
A. 1.2, 1.3, 1.4, 1.5.
Q. Now, is that specifically with respect to cystic fibrosis, or is that with respect to all --
A. No. That's all diseases.
Q. And how many do you do a year?
A. I can tell you what we did in 2004.
Q. How many did you do in 2004?
A. I wrote the numbers down. We did 582 cycles.
Q. And you have that specifically available to you, you wrote it down?
A. I wrote it down before I came over here. Because I figured you'd ask.
Q. Okay. And what did you write it down on?
A. (No response).
Q. What did you write it down on?
A. I just wrote it in the corner here on this piece of paper.
Q. Before you came over here?
A. No. I had it in my mind. But I knew the question was coming, so I scribbled it over here so I wouldn't forget

Page 44

the numbers.
Q. And do you know how many you did in 2009, last year?
A. No. But almost twice that.
Q. And how many failures did you have in 2004?
A. Three.
Q. The Grossbaums was one of them?
A. Yes.
Q. And what was the analysis done on the other two that had failed?
A. One of them was a healthy child that we predicted was a carrier, and one of them was an affected that was picked up on amniocentesis or CVS.
Q. And was it picked up?
A. Yeah.
Q. And did the parents abort in that case?
A. I don't remember. There's no link between those. An amniocentesis is not a search and destroy mission.
Q. I think we explored that at the last deposition, didn't we?
A. I don't remember.
Q. You haven't read your deposition --
A. Months ago.
Q. -- prior to coming here today?
A. No.
Q. The 582 cycles that you described, were they for all

Page 45

forms of genetic disorders, or just for cystic fibrosis?
A. No. For all forms.
Q. Now, the Grossbaums were described as having a mutation that was -- can be said to be compound heterozygous, is that right?
A. Yes.
Q. Do you know how many of the cystic fibrosis studies that you did in 2004 were for couples who had compound heterozygous mutations?
A. I don't know those numbers off my head, no.
Q. Do you know how frequently you see compound heterozygous mutations to be analyzed?
A. Fairly frequently. Now.
Q. Now?
A. Um-hum (affirmatively).
Q. How about in 2004?
A. We would see them then, too, but it's gone up substantially, the numbers. Because the ability to find the mutations in these different diseases has gone up, because the technology for looking for the mutations is easier. So just a few years ago there weren't very many places that would -- well, cystic fibrosis is different -- but for many of these disorders there wasn't anyone who was willing to screen by DNA sequencing the entire gene looking for what the other mutation might be, so PGD

Page 46

was not offered then.
Q. And what year are you talking about?
A. 2003/2004/2005.
Q. PGD was not offered for a particular class of mutation?
A. We wouldn't do it if we didn't know what the other mutation was.
Q. Well, the mutation for this couple, both mutations were well-known back in 2003, were they not?
A. Absolutely they were.
Q. And they were well-known for a number of years before 2003, wasn't that so?
A. That's correct.
Q. So with respect to that mutation and that compound heterozygosity, those mutations were being analyzed and PGD, were they not at that time?
A. They were.
Q. And you weren't, by 2003, declining to study compound heterozygosity, were you?
A. No.
Q. And you were studying that type of gene mutation and reporting on it without the use of linkage analysis, is that right?
A. In 2004?
Q. 2004, yes.
A. Early 2004 yes, that would be right. Um-hum

Page 47

(affirmatively).
Q. And that would be for 2003 and 2002, is that right?
A. That's correct.
Q. And the use of linkage analysis certainly increases the accuracy and reduces the risk of misdiagnosis, isn't that true?
A. Not in 2004. It was just beginning to be proven to be so, and the manuscripts were beginning to come out showing that it worked.
Q. When you say they were beginning to come out, we do agree that Dresen's group in Europe was reporting in 2001 the success rate for using linkage analysis, weren't they?
A. They were taking two cells in order to get those results, so they were biopsying a couple of cells from each embryo. Most of the clinics we work with don't want to do that, including NYU. And the group in Chicago that was doing it was biopsying a polar body, oftentimes a first polar body and a second polar body and a blastomere.
Q. Is that in all compound heterozygous cases?
A. I don't know. But that was their standard that they reported at meetings and in their papers. And they argued at the meetings that this was a better approach. And this was all kind of coming out. But we had a 1.2 percent error rate, which was significantly less than

Page 48

anybody else was reporting, so -- and we were having difficulties getting multiplex PCR to make that better or look like it make it better. Theoretically we could see where it was quite valuable, but we were not happy with the results, in those early papers we weren't able to reproduce them.
Q. When you say you were not happy with the results, what do you mean by that?
A. Well, in anything in science and medicine, a manuscript comes out, and this doesn't suddenly make it the gold standard of practice. Because if it was a gold standard of practice, that paper wouldn't even be allowed to be published because it isn't new or exciting. So the papers that were coming out in 2001 were theoretical to start with, then they became one or two cases, take a couple of cells, do the analysis and see what the results are.
The RGI group actually were quite leaders in this, and were showing some beautiful data at the time. But others of us were having difficulties duplicating that. We weren't as good as them perhaps, I'm not sure. But we were not comfortable, with our preliminary when we developed the test for a couple, we were not comfortable with the multiplexing of more than two different mutations at the same time. We didn't have the ability,

Page 49

nor did we think we needed, because we had such a low error rate, that we weren't ready to be offering something that was just being discussed.
Q. Well, if there was a laboratory as close as Chicago, you having good results with linkage analysis, didn't you see it as on obligation of your relationship with the couples such as the Grossbaums who had compound heterozygosity, to afford them the opportunity to go there?
A. That's up to the doctor to decide what laboratory they're going to use, first of all. And secondly, it wasn't hardly proven until the Goossens paper came out that that was actually working clinically.
Q. And when did the Goossens paper come out?
A. Late 2003. I think. I can't remember. I think it was in the fall of 2003.
Now, the --
Q. And by the Goossens paper you're talking about Improving Clinical Preimplantation Genetic Diagnosis for Cystic Fibrosis by Duplex PCR?
A. Yes.
Q. And you were aware of that paper when it came out?
A. I don't remember when I first saw it, but when I did it was a good group that had some clinical successes, and it was beginning to -- the handwriting was beginning to become quite clear that this was the future. Now, we

Page 50

were already trying to do it, but we do lots of things in the laboratory as we test for several years before we move it to clinical activities.
Q. Now, when you say you were already trying to do it, can you explain what you mean by that?
A. So we would take hundreds of single cells that we would micropick, as though they were a cell from an embryo. Lymphocytes, fibroblasts, amniocytes, in which we knew what the mutations were in those cell lines. We would pick them and study them as though they were a biopsy from an embryo, blinded. And then we would analyze to see if we could reproduce the results better than the error rates that we already had in our program. And what we were finding was that the -- we would pick up some markers that were very nice to have, but we would lose other pieces of data, oftentimes the mutation. And so to get them to all work together just was a problem. We weren't comfortable that the technology was improving anything. So that's what happens over a period of a few years, you try, you analyze, you compare, you check out to see if the other laboratory's work is reproducible. And sometimes it is and sometimes it isn't. And in the field of IVF there's all kinds of these false starts, but you don't know which one's a false start. So you don't just move it to the clinical arena because somebody

Page 51

publishes a couple of papers, most of them theoretical.
Q. Well, you do agree in the year 2000 Chicago had published its atlas describing the use of linkage analysis, isn't that so?
A. Everybody knew about linkage analysis.
Q. And do you agree that Dresen's paper was in about the year 2000 or 2001, wasn't it? Dresen.
A. I don't recognize that name. I probably was a graduate student or something.
Q. Or am I mispronouncing it? Is it Dresen? It's D R E S E N. That's the Department of Molecular Cell Biology and Genetics at Maastricht University, that would be in the Netherlands, and it was published in 2000.
A. Let's see.
Q. (Indicating).
MR. STEIN: Let the record show I've handed Dr. Hughes a copy of the journal publication that I've just referred to and he's reading it.
THE WITNESS: Yeah. We could test single lymphocytes and fibroblasts like this. This isn't an actual -- there's no pregnancies here, there's no proof that it works in an IVF embryo. Now, later, soon thereafter, there was. But this is studying lymphocytes, and some blastomeres. Let's see here. Blastomeres were obtained from human embryos that were donated in IVF. So

Page 52

this is all -- this is a nice paper. It was new, exciting, new possibilities for changing the technology. But it was a long way from clinical implementation, certainly in the United States, except at RGI.
Q. Well, Doctor, let's separate that. It would appear from this article in 2000 out of the Netherlands, as well as the RGI publication in its atlas, that the technology was known by 2000 by these various groups as to how to do it, isn't that so?
A. The ability to do multiplex PCR had been around long before that.
Q. All right. So if these groups --
A. And we were doing it.
Q. Well, when you use the term multiplex analysis --
A. It means having a single cell and looking at multiple places in that genome.
Q. Is that the same as linkage analysis, in your terminology?
A. Looking at those multiple places produces the linkage information.
Q. Okay. So then using that technique as a standard use in their laboratory, RGI was doing it, they had the technology, didn't they?
A. We had the -- lots of people have the technology. The question was, was it ready to be added and was it proved

Page 53

to be useful and was it better.
Q. Well, if it reduced the --
A. Let me give you an example. The same group who I think are outstanding in Chicago, Svetlana Rechitsky and Buck Strom, they were great scientists, they were working on a technology called FISH. And when you quote these numbers from Cornell with thousands of cycles, those were done with FISH. In fact, the world jumped on the ability to count chromosomes using FISH technology. And now, all of the medical societies that oversee this have said that there's no scientific evidence that this works. There's no scientific evidence that a patient should have FISH testing. And it's written in the practice guidelines of the field by the authorities who you would recognize that direct the way something is performed in medicine. In the society's guidelines of practice it says that there's no scientific evidence that FISH works. Now, it's controversial. We never believed in that technology either, and never performed it. Why? Because we couldn't get it to work with the kinds of reliability we wanted. In the same way in IVF, there's all sorts of steps that are taken to try to improve the technology an get people pregnant with healthy babies. It's done all the time. Many of those fall by the way side as being not helpful, can't be reproduced. So in the first few

Page 54

years of the year 2000 people started talking about doing this in PGD, and everybody, I would hope, was trying to get this to work because of the theoretical idea that it was going to help and avoid one of the problems with PGD, which is allele drop out. But you have to have a technique that improved it significantly more than what you already had. No more than Memorial Sloan Kettering invents a new cancer agreement and no other cancer programs in the country use it for some five years or ten years while they're assessing it. It doesn't make it standard, just because you publish a paper, doesn't make it standard of care.

Q. Well, when you publish it in an atlas on how to do it, would you say that then it has moved from theoretical to clinical practice?

A. No.

MR. LEUCHTMAN: Object to the form of the question.

THE WITNESS: The atlas is written by the people who are promoting their own science.

BY MR. STEIN:

Q. All right. Now, in fact, had you been provided with blood samples from family members of the Grossbaums, you would have done linkage analysis, wouldn't you?

A. We would have tried.

Page 55

Q. And --

A. I'm not sure we would have used it in their case, but we certainly would have tried. We would have looked at genomic markers in their parents and tried.

Q. But no request was ever made to have the parents provide blood samples, were they?

MR. HAMAD: Objection to form.

THE WITNESS: I don't think that's true, but I don't know for sure.

BY MR. STEIN:

Q. Well, you have your chart in front of you. Did you ever see any specific request made for the parents' blood samples in your initial interview?

A. Let me look. It's going to take a bit.

Q. And by parents, I mean the parents of the couple, as opposed to the couple who would be the parents of the expectant baby.

A. Yeah. But they're not parents yet, so we don't call them parents.

Q. Okay.

MR. HAMAD: Can I have the question read back? I thought he already answered it and he said he didn't know.

THE WITNESS: I have a little cryptic thing here that says, blood possible from parents, question mark,

Page 56

seems not. I'm not sure what that means. I think -- I'm assuming it meant that we had a discussion about it, but I would have written more if the discussion was very long. So I think it was mentioned, and like many of the patients they are very uncomfortable about involving their parents, the next generation up. They have a child or a sibling that could be helpful they'll offer, but -- but it looks like there was some pushback, but that would be my guess from that little cryptic note.

BY MR. STEIN:

Q. By the way, you're looking at a photocopy of your records, is that right?

A. Yeah.

Q. And where are the originals of these records?

A. They will be -- well, they're scanned, and they'll be in the electronic chart.

Q. Okay. So the original copies of your handwriting as it was made on the day you made it are not available anymore?

A. I don't know about 2004. It could be. It could be -- I don't know if we systematically scanned 2004 into the electronics. I can find out for you. If it isn't, we have it as paper.

Q. Okay. And where would you have it as paper, over at your --

Page 57

A. Yeah.

Q. -- laboratory?

A. Over in the lab.

MR. STEIN: I'll write a request so I can understand whether that exists or not.

BY MR. STEIN:

Q. Doctor, you have in front of you the reports that you sent out in this case?

A. They should be here. Just a second.

Yes.

Q. Now, Doctor, is that the standard form by which you report the results of your analysis? By that I mean --

A. This one?

Q. Let's mark it for identification.

DEPOSITION EXHIBITS P5 THROUGH P9 WERE MARKED BY THE REPORTER FOR IDENTIFICATION

BY MR. STEIN:

Q. Doctor, I show you a page from what's been represented to be the medical records of Genesis Genetics Re Grossbaum, that Midterm Medical may be mine and not yours, but the records of Genesis Genetics regarding Grossbaum, and I show you the page we've marked P5.

A. Yes.

Q. Do you have it in front of you?

Page 58

A. Yes, I do.
Q. Does that represent the standard form by which Genesis Genetics reports the results of its testing?
A. No.
Q. And in what way is it not the standard form?
A. Well, several clinics, NYU being one of them, wanted to have us send them a temp report early, as quickly as we had the data. Because it would always take us another half an hour to an hour and a half, depending on how many cases we had that day, to produce the formal report, write up what it means. So they and several other clinics want to know what's happening in written form, not over the telephone, so that they can call the family, my understanding is so that they can call the family and tell them to come in for an embryo transfer or not, rather than making them wait another hour or an hour and a half for a formal report that morning. Because this test is done all night long. So in the morning the data's read, most clinics receive a formal report as the only report. Some groups ask for something quicker so that they could call, so you'd have to check with the clinic, but my understanding was they would then call this couple and tell them, yes, you can come in, or no, there's nothing to transfer, or your embryos have not developed or whatever. So the lab person will put

Page 59

together a quick report so that the clinic is then aware that they can proceed and get ready for the transfer. So it's faxed on a regular fax machine, we send off a fax to them, a person in the lab reads the data, it's read by another person, and then they send it off real quick.
By then I come in or one of the people who's got the authority to write a formal report, and we sit down and take the information, look at it and write a formal report that's supposed to go in the medical record. So actually I must admit I was surprised to see that NYU even kept it, but whatever.
But Alexis, who runs the center there, she's kind of -- and she wanted -- didn't want any verbals, she wanted it in writing so that they could do the transfer.
Q. So are you saying that it was Alexis who --
A. No, I don't know who it was. But Alexis was the person who would normally interact with us and would say, you know, I want to know if I can call the patient, send us a report.
Q. So this particular form of report was not by any means standard that you sent to most or all of the IVF utility clinics that send you samples, is that what your testimony is?
MR. LEUCHTMAN: I'll object to the form of the question.

Page 60

MR. HAMAD: I'm going to object on the grounds that this also -- although is an expert deposition, I think Dr. Hughes just went beyond to change the facts of this case, to change his fact testimony. So I'm objecting. We may have to come back here to re-depose Dr. Hughes on some of these issues, which, obviously, showing up for an expert deposition I don't expect the facts of case to be changed on me in the last second. So for the remaining of this deposition, I will preserve my right to come back here, have further deposition of Dr. Hughes on this issue.
THE WITNESS: I would like to say that --
MR. STEIN: Well, wait a second. You say when answering to questions, you don't participate except for --
MR. LEUCHTMAN: Well, I think he's entitled to respond that. He's been accused of changing the facts.
THE WITNESS: I'm not changing anything.
MR. STEIN: It was inappropriate for counsel to make this statement.
MR. HAMAD: I'm just reserving my rights, that's all. That's it.
MR. STEIN: Where is there in the practice of deposition taking that you have to reserve a right on the record during the course of the questioning that's being

Page 61

conducted by a lawyer of a witness?
MR. HAMAD: There is plenty of references in the court rules regarding the rules of experts and rules of fact deponents, correct?
MR. STEIN: At the end of the questioning --
MR. HAMAD: Fair enough.
MR. STEIN: -- if you want to, when the witness is excused, put on the record something you feel you need to do to preserve a right, as opposed to sending a letter tomorrow or making a motion --
MR. HAMAD: Fair enough.
MR. STEIN: -- then --
MR. HAMAD: I guess I jumped the gun. I'll wait an hour, I'll say exactly what I just said, and then we'll be back here.
MR. STEIN: Well, I think you can do what you like, but --
BY MR. STEIN:
Q. Doctor, do I understand that this document which we've marked P5, in the form in which it appears as part of the Genesis Genetics records, was not a standard form which you generally used to report to most of the clinics that you did PGD studies for in 2004?
MR. LEUCHTMAN: Object to the form of the question.

Page 62

MR. STEIN: Okay.
BY MR. STEIN:
Q. Can you answer the question, please?
A. A formal report is done on stationery with an explanation with lots more information. This was -- the purpose of this was for the NYU team to be able to see that there were embryos predicted suitable to be transferred, and act on it if they wish. So it's not like it's wrong, it's that it's not complete. And it takes a while to do a longer one. And so we sent this to them fully expecting them to read it and act on it. That's fine. There's nothing wrong with it.
Q. This bears electronically signed your signature. Can we understand that by the presence of your electrically signed signature this is a document that you endorse by way of the content, or either created yourself or had someone create and then have you read it and endorse it?
A. This was put together by a lab person who electronically puts my name on it and sends it to the clinic.
Q. Now, in connection with reporting the results of lab studies , is it important in the custom and habit of the laboratory to document the transmittal of your report to the clinic?
A. I'm not sure what you mean.
Q. Well, is it customary -- withdraw that.

Page 63

Is it a requirement of your practices and procedures as Genesis Genetics as you go forward in doing your analysis that when the report is transmitted a record is kept of the date and time that the report is transmitted?
A. No. No laboratory does that. They send out reports by mail oftentimes. They don't have a -- they don't send out report -- hospitals don't send out reports. Laboratories don't send reports to doctors and hospitals with everything being certified or -- we don't do that.
Q. So when you report on your analysis to the clinics so that the patient can be called in, you don't keep any record or require that a record be maintained of the transmittal of the results of your analysis at a particular date and time?
A. No. We send the report to them -- if they didn't get it they'd be calling, I can promise you -- and then we put the chart away.
Q. I see.
So if we look at --
A. Any more than if I ordered any other test.
Q. So you don't require in the operation of Genesis Genetics that there be a verification of the transmission of the report in your chart?
A. We don't keep any kind of verification that we wrote a report or that we sent it, no. If the recipient didn't receive a report we would hear about it.

Page 64

Q. Can you explain to me what the document in your chart at Genesis Genetics which has been provided to me, which we've marked P6, what's the purpose of that and what is it?
A. So the person in the lab who faxed this on the paper fax machine got a verification and threw it in the chart with it.
Q. Okay. So then in fact you do --
A. This is not -- you asked is this a requirement or a standard procedure. It's not a standard procedure to have this piece of paper in there at all.
Q. So then that's a -- okay.
Now, do you have any documentation in your chart as to -- withdraw that.
There appears also in your chart a document which we previously had used in one deposition marked P8 for identification, a message page, is that correct?
A. Yep. Yes.
Q. Do you have anything in your records to verify the transmittal of that record, of that document which we've marked P8?
A. You mean like another fax?
Q. Right.

Page 65

A. No.
Q. So there's no form of verification in your chart that the document, P8, was received by NYU, is that right?
MR. HAMAD: Asked and just answered.
MR. LEUCHTMAN: Not exactly.
THE WITNESS: I don't have any document that says -- they didn't write me back and say we got it.
BY MR. STEIN:
Q. Or any other mechanism, such as a fax verification or any kind of fax entry which would --
A. Well, when I do this, and I know I did this one, because it's come off of my computer, when I do this I write the message, I go to Outlook, find the proper address and fax number, it goes into the Microsoft Word's electronic computer fax submitting thing and out it goes, it puts this in there.
Q. So I take it that this document, P8, also may be found in your computer, is that right?
A. I would assume so. From 2004 I don't know, I've had several computers since then, but maybe. And in fact it was -- this part's generated by the program, so it pulls the phone number and the time off.
Q. Okay.
A. And I do that because the -- it's a crisper picture.
Q. Okay. Now showing you P9 for identification. That is

Page 66

what you represent to be your formal report?
MR. HAMAD: Objection to form.
THE WITNESS: It's our formal report.
BY MR. STEIN:
Q. And that is your complete report on the Grossbaums' matter?
A. Yes.
Q. Okay. Now, turning to the P8 -- do you have a copy in front of you?
A. Yes.
Q. In the first paragraph of P8 you describe the results as disappointing, is that correct?
A. Yes.
Q. And then you go on in your second paragraph to say, if the couple chooses a transfer with this partial data set, do you not?
A. Um-hum (affirmatively).
Q. Does that statement assume that the couple will be advised that there is only a partial data set?
MR. HAMAD: Objection to form.
THE WITNESS: I'm not assuming anything.
BY MR. STEIN:
Q. Well, for the couple to choose to transfer this partial data set there has to be some communication to them that there is a partial data set that was disappointing,

Page 67

doesn't there?
MR. HAMAD: Objection, form. Misstates his prior testimony. You can answer.
BY MR. STEIN:
Q. Go ahead.
A. I'm not sure I understand. We're dealing with an outstanding group of people who understand PGD very well. They're going look at this table and see that --
Q. Doctor, my question --
MR. STEIN: Can I have the last question read back please?
(Record repeated as requested).
THE WITNESS: When a doctor reads a diagnostic report that they receive, they read it and understand what it says. I mean, that's why they order the test. So you send them the information, whichever one you want, and it's pretty clear that there's a partial data set. It doesn't take rocket science to see that.
BY MR. STEIN:
Q. Doctor, my question just called for a yes or no answer.
A. Then I don't understand the question.
Q. All right. If, as you say in your message, a document we marked P8, if the couple chooses a transfer with this partial data set, you are referring to a choice made by the couple who you provided laboratory services to, are

Page 68

you not?
A. I'm referring to the choice that the couple would make after hearing the information about the quality of their embryos, and the molecular results and the options that they have in front of them about what they would like to do. And it isn't necessarily so, I mean, I don't know, but it isn't necessarily so that the clinic would agree to what that would be. They might and they might not.
Q. Might agree and might not agree to what?
A. Well, if the doctor said we're not going to transfer this embryo, some clinics would say we're not going to transfer the embryo. Other clinics would say, well, no, the embryo belongs to you and you can take it if you wish. I stay away from those things, but I point out the limitations of the testing.
Q. Are you presuming by that comment that the couple will be advised of the disappointing result of your test?
MR. HAMAD: Objection to form, asked and answered.
THE WITNESS: I'm not assuming anything.
BY MR. STEIN:
Q. Okay. Now, you say that in that message that AVO is possible in compound heterozygous testing such as this, and even more likely given the embryo quality. That's what you write, is that right?

Page 69

A. Yes.
Q. Now, in the preliminary report that you sent, as you described it, we've marked P5, you discuss allele dropout, don't you?
A. Yes. Well, I mentioned it in -- it's mentioned in sample two.
Q. Now, just so I'm clear, is it not anticipated that the clinic will proceed with IVF based on the form of report that is present and marked P5?
MR. HAMAD: Asked and answered, three questions ago.
THE WITNESS: This report is sent to them just like any laboratory report. They review it, they make a decision in the best interests of the patient, I hope, and I don't have any assumptions about which ones they're going to transfer. In fact, earlier this week a couple elected to take two embryos that were affected, so --
BY MR. STEIN:
Q. Aside from what the couples intend to do as a result of the decision, you are presuming when you send P5 that the fertility clinic will act on the content of the information contained in P5, are you not?
A. No. I'm sending them information. What they do with it at that point is completely up to them. They can say we don't like any of this, they can say we're going to

Page 70

transfer five embryos, they can say we're going to freeze all of them, or we're going to discard all of them, or they can have a conversation with the patient. They're going to decide what they want to do with the data.
Q. But they're going to rely on the information in the form presented on P5, are they not? Wouldn't you anticipate that?
A. I would anticipate that that would be a piece of their decision-making process, yes.
Q. And in that piece you write with respect to embryo sample number two that possibly affected was ADO paternal, is that right?
A. Yes.
Q. And that's because there was no deletion, is that right?
A. It's because we're seeing the mutation in exon 11.
Q. All right.
A. And there could be a little dropout of 10.
Q. But as far as you know from 10, what you've got in the results of your analysis was that the mutation was not present in 10, is that right?
A. The mutation is present in 11.
Q. Right.
A. And we couldn't see the mutation in 10.
Q. So if the mutation is present only in 11 and you don't see the mutation in 10, then why would that sample number

Page 71

two not be okay for transfer?
A. It could be. But it's possibly affected, and we wanted to point that out. Because we absolutely positively see the paternal mutation and we do not see the normal copy of the gene. There should be a G there. We should see the G, and we don't see it.
Q. Right.
A. And it's the only embryo that had that setting.
Q. Well, when you go down to number eight, you see GT?
A. Yes.
Q. What does that mean, in CF11?
A. Okay. So we know that the mutant allele, the mutant gene is present from the father -- I'm sorry, from the mother.
Q. Right.
A. And we see a G that would have come in from the sperm. So it's a heterozygote at that location, which is perfectly reasonable.
Q. Okay. So --
A. So we know that that embryo has a normal copy of -- so we know it's a carrier of 11, we know it's a carrier of the mother's mutation, and we don't see a mutation in 10.
Q. Right. So how do you know that there isn't allele drop out with respect to a 10 at that point?
A. Well, I suppose there could be, but the fact that we see both alleles -- we see an allele from the mother, and

Page 72

from the father in the other exon.
Q. Well, that's the same as two. You see an allele in one --
A. No, it's not the same. No.
Q. And you have no deletion in 10, and you're concerned about allele dropout there, why aren't you concerned about allele drop out with 10?
A. Because there must be a G in exon 11. Every sample must have a G in exon 11. If it doesn't, there's allele dropout.
Q. All right. Well, and if you've got allele dropout in 11, it means that that may be a carrier of the mutation, right?
A. It could be. That's why -- for which one are we talking about?
Q. 8.
MR. HAMAD: A risk of allele dropout or allele dropout? I don't know what you're saying.
MR. STEIN: It could be --
THE WITNESS: So in embryo 11 we have all of the data that would be consistent with it being a carrier female, carrier of the mother's mutation.
MR. STEIN: Right.
MR. LEUCHTMAN: Well, hold on.
MR. HAMAD: Embryo 11.

Page 73

THE WITNESS: I thought we were on 8.
MR. HAMAD: Exon 11. You're talking about CF11, right?
THE WITNESS: Yes.
MR. HAMAD: Okay.
BY MR. STEIN:
Q. Okay. So now that's okay for transfer, correct? You say so in your --
A. Yes.
Q. But now 7, you see a G, that means that's a carrier at worst, right?
MR. HAMAD: Objection, form.
BY MR. LEUCHTMAN:
Q. 7 you've got described as carrier at worst, right?
A. Yes, that's the wording used.
Q. Okay. And in exon 7 you don't know what the -- I'm sorry, sample number 7, as far as the father's gene, you don't have any amplification, right?
A. No.
Q. So why isn't that given the same description, okay for transfer, as number 8?
MR. HAMAD: Objection, form.
THE WITNESS: There would have had to have been a double dropout.

Page 74

BY MR. STEIN:
Q. Well, if you have no amplification, is that considered a dropout?
A. Yes.
Q. Allele dropout?
A. Yes.
Q. And so there is a greater risk of an affected baby in number 7 than 8, I take it?
MR. HAMAD: Objection to form, misstates his prior testimony.
MR. LEUCHTMAN: I'll object as to form also.
BY MR. STEIN:
Q. Go ahead. Want to answer the question?
A. I wouldn't say that.
Q. Why not?
A. We think -- I mean, when we look at the numbers for embryo 7, the risk of that embryo having a double dropout would, in our hands, be quite small, less than one percent.
Q. Well, why didn't you call it okay for transfer?
A. When we said okay for transfer it meant those were the preferential embryos. A doctor would look at carrier at worst and say, well, we could transfer that one if it worsens the status as a carrier. We were pointing out the ones we were most happy with the data.

Page 75

Q. So you were less happy with the data in 7 than you were with 8, is that right?
MR. HAMAD: Objection, form.
THE WITNESS: What we do is we try to point out what ones we like the best, that's true. The terminology used in the formal report is probably more accurate, but the result, the decisions that they made from the testimony that I read in the depositions of the NYU people, we wouldn't argue with any of it.
BY MR. STEIN:
Q. Then if in fact you had what you would consider 3 based on 7, 8 and 10, 3 embryos that I take it you wouldn't argue with if they were utilized, why would you be concerned as you were in the message about the couple choosing to transfer the partial data set?
MR. HAMAD: Objection to form. Concern is not a word that was used, object to that characterization.
MR. STEIN: Okay.
MR. LEUCHTMAN: I will, too.
THE WITNESS: Yeah, I'm not concerned. We point out that those are the embryos that -- I mean, anyone knows that if you didn't get data it's less valuable than if you do. So I pointed it out in word form, but it's obvious from the data page.
MR. STEIN: I'd like to go over the rest of my

Page 76

notes here.
BY MR. STEIN:
Q. Now, just one last question. I think you indicated in your testimony, and I may be wrong, that there were some things in the report of March 2nd that was actually sent that you would not entirely agree with.
MR. LEUCHTMAN: In the report that was sent?
MR. STEIN: In the report I got.
MR. LEUCHTMAN: Object, it mischaracterizes his testimony.
MR. STEIN: Yeah, fine.
MR. LEUCHTMAN: Thank you. I need to get your approval of the objection.
BY MR. STEIN:
Q. Is there anything that as you read it now that you do not agree with in the report?
MR. HAMAD: I'll also join Mr. Leuchtman's testimony. I think the witness has never said that he didn't agree with anything in his report.
MR. STEIN: I asked is anything that he doesn't agree with. That's a simple question, Mr. --
MR. HAMAD: What is the point of the question?
MR. STEIN: Please don't interrupt.
MR. HAMAD: I'll try not.
THE WITNESS: I don't want to answer unless I've

Page 77

had a chance to study every single word. I assumed that a letter that was sent to my own counsel, I had no idea that this thing was so important, that this is going to turn into a major deal. Many people write things for me all day long, all the time. And I skim them and review them and put my name on them. This is not unusual. And when the letter's going to my own attorney, I didn't have a clue what the legal mumbo-jumbo of that meant.
MR. LEUCHTMAN: Well, all right. Let's --
THE WITNESS: That's about as much as I want to --
BY MR. STEIN:
Q. Are you saying you didn't understand that this letter was going to be turned over to counsel --
MR. LEUCHTMAN: Objection, that gets into attorney-client privilege. He's not going to answer that question.
MR. STEIN: I'm going to restate the question.
MR. LEUCHTMAN: He's not going to answer the question.
BY MR. STEIN:
Q. When you signed this letter addressed to your attorney, you had no idea that that letter then was going to be turned over in that form that you signed to counsel for the plaintiffs, myself, is that right?

Page 78

MR. LEUCHTMAN: Objection, don't answer the question. That asks for what was said in conversations between attorney and client.
MR. STEIN: Okay. I've got another question.
BY MR. STEIN:
Q. There's a statement made in the second to last paragraph, based on the literature, most misdiagnosis are due to intercourse or unprotected sex. Do you agree with that?
A. No.
Q. Pardon me?
A. No.
Q. Okay. But yet it was in the letter that you signed, is that right?
A. Yeah. It's quite common, but it's not -- I would say not the most common. But I don't know how you prove it. And as a scientist you need to be able to prove it.
Q. And also, you have no evidence that the Grossbaums had intercourse with unprotected sex during their period of --
A. I did not have cameras in their bedroom, no. I don't know -- there's many reasons, you're focusing on a laboratory here, but there's many reasons for this, and that's just one of them.
MR. STEIN: Okay.
MR. LEUCHTMAN: Let's take a recess.

Page 79

(A short recess was taken)
MR. STEIN: Just a couple more.
BY MR. STEIN:
Q. In this case did you have an opportunity to see Dr. Charles Strom's report?
A. Yes.
Q. And you know him?
A. Oh, yes.
Q. And you respect his opinions in general, if not in this case?
A. I think he's a class guy.
Q. Okay. And I take it you disagree though with the content of his report, is that right?
A. I think that he's voicing his opinion based on the experience he had in his own laboratory, and it's excellent, and so I can't quibble with the data that he was generating.
MR. STEIN: All right. I don't have anything more.
MR. HAMAD: Doctor, I have a question for you actually.
EXAMINATION BY MR. HAMAD:
Q. I'd like to you take a look at your -- actually we'd like you to take a look at your report.
A. Which one?

Page 80

Q. Your expert report in this case. Just let me know after you've had a chance to review it if there's any opinions in there that you don't agree with or that you would like to retract. Because we just want to make sure the report we have is, you know, is a good report from you, reflects your opinions?
A. I haven't read every single one.
MR. LEUCHTMAN: No, no, no. That's not the one he's talking about. The letter to me.
THE WITNESS: The letter to you.
MR. HAMAD: I'll rephrase it.
BY MR. HAMAD:
Q. Doctor, we would like you to take a look at your report, the expert report you served in this case, and moving on with this lawsuit we'd like to know if you stand by those opinions, with the exception of the sentence --
A. Well, and I -- so with the exception of I refer, so that kind of a little thing, so in here there's an I refer.
Q. Yeah.
A. Well, okay. There could be a couple of little things like that in here.
Q. Besides that.
A. But in general I concur with the report and read it quickly and signed it.
Q. And you concur with the opinions expressed in that

Page 81

report?
A. Yes.
Q. Okay. And you still do today?
A. Yes.
Q. And you attempt to do so at the time of trial?
A. Yes.
MR. HAMAD: Okay. No further questions.
MR. LEUCHTMAN: I don't have any questions.
(The deposition was concluded at 3:40 p.m.)

CERTIFICATE OF NOTARY

STATE OF MICHIGAN)
) SS
COUNTY OF MACOMB)

I, LAURA J. STEENBERGH, Certified Shorthand Reporter, a Notary Public in and for the above county and state, do hereby certify that the above deposition was taken before me at the time and place hereinbefore set forth; that the witness was by me first duly sworn to testify to the truth, and nothing but the truth, that the foregoing questions asked and answers made by the witness were duly recorded by me stenographically and reduced to computer transcription; that this is a true, full and correct transcript of my stenographic notes so taken; and that I am not related to, nor of counsel to either party nor interested in the event of this cause.

_____
LAURA J. STEENBERGH
CSR 3707 Notary Public,
Macomb County, Michigan
My Commission expires: 2/14/15

EXHIBIT I

Professor Mark Hughes, MD, PhD
Director, Genesis Genetics Institute
Director, Applied Genomics Technology Center

Professor Mark Hughes graduated in Biology and Chemistry from **St. Johns University**, and then received a Masters in Biophysics at **Stanford University**, followed by a Ph.D. in Molecular Biochemistry at the **University of Arizona** Medical Center. He continued his training at the **Baylor College of Medicine** in Houston as a postdoctoral fellow with Bert O'Malley, where his pivotal work was published in *Science and Nature* and involved the cloning of the vitamin D and progesterone receptors and characterization of the first mutations found in human gene transcription factors. Following this training Hughes completed his M.D. at Baylor, followed by house staff training in Internal Medicine and clinical subspecialty training at **Duke University**. He then returned as junior faculty to Baylor's newly formed Genetics Institute led by Thomas Caskey. Among his accomplishments was the realization that single cells could be molecularly data mined for diagnostic advantage: This led to a multi-year collaboration with IVF clinicians and embryologists at the Hammersmith Hospital in London; the field of Preimplantation Genetic Diagnosis was born. *In 1993 Hughes' research was recognized by Science magazine as being one of the "ten most significant advances" in all of science that year; spanning all the physical, biological and mathematical sciences for that year.*

It was then that Professor Hughes was recruited to be one of the first 11 members of the **Human Genome Institute at NIH.** The Genome Project was getting underway and Hughes was recruited to lead the section on Translational Genomic Diagnostics. He also chaired Human Genetics at **Georgetown University**. Doctor Hughes then moved to Michigan to take a position as Professor and Director of Molecular Medicine and Genetics, Professor of OB-Gyn, and Professor of Pathology. He was named as the Director of the state of Michigan's 'Life Sciences Genomics Hub', focused on cutting-edge molecular medicine.

Hughes' work has centered on understanding gene expression in the early human embryo. His work on embryonic stem cells was acknowledged in 2001 when, along with Ian Wilmut (of Dolly the sheep fame) Hughes was awarded the "Pioneer in Stem Cell Biology" award. Professor Hughes, along with Professor Lord Robert Winston and Dr. Alan Handyside developed and performed the world's first cases of PGD. As we know, this field is now practiced world wide – today's speaker continues to push the frontiers of this technology and guide it in all its ethical ramifications, while he has expanded this work to systems-wide molecular understanding of early embryo development. His goal is to better understand, and hopefully prevent, many inherited birth defects of children. You may have seen him on the two hour BBC special, "Good Morning America", the "Today show", "CBS Evening News", and the subject of television newsmagazine segments for 60 Minutes and 20/20, and full hour programs on the Discovery Channel. His most recent medical advances have been in using Preimplantation Genetic Diagnosis to assist couples in avoiding serious diseases in their children and, at the same time, obtain a stem cell cure for a sick child already in the family. He performs this "miracle" every day now for hundreds of families Four years ago, because of federal funding limitations on embryonic stem cell science, he moved the PGD aspects of his work into the Genesis Genetics Institute where the diagnostic aspects of PGD are provided to over 270 human reproductive centers in North and South America, Europe and now Asia.

Mark Hughes has an international reputation for his work on single-cell analysis and preimplantation genetic diagnosis. Through this work, Hughes diagnoses specific hereditary diseases in a single cell biopsied from an eight-cell embryo prior to implantation in the mother's uterus. This specialized procedure allows parents at high genetic risk to greatly reduce their odds of passing the genetic disease of concern on to their children.

Hughes graduated in Biology and Chemistry from St. Johns University, and then received a Masters in Biophysics at Stanford University, followed by a Ph.D. in Molecular Biochemistry at the University of Arizona Medical Center. He continued his training at Baylor College of Medicine where his pivotal work was published in *Science and Nature*. Professor Hughes completed his M.D. at Baylor, followed by house staff training in Internal Medicine and clinical subspecialty training at Duke University. He then returned as junior faculty to Baylor's newly formed Genetics Institute. Among his accomplishments was the realization that single cells could be molecularly data mined for diagnostic advantage. This led to a multi-year collaboration with IVF clinicians and embryologists at the Hammersmith Hospital in London; the field of Preimplantation Genetic Diagnosis (PGD) was born. *In 1993 Hughes' research was recognized by Science magazine as being one of the "ten most significant advances" in all of science that year; spanning all the physical, biological and mathematical sciences.*

It was then that Professor Hughes was recruited to be one of the first 11 members of the Human Genome Institute at NIH. The Genome Project was getting underway and Hughes was recruited to lead the section on Translational Genomic Diagnostics. He also chaired Human Genetics at Georgetown University. Doctor Hughes then moved to Michigan to take a position as Professor and Director of Molecular Medicine and Genetics, Professor of OB-Gyn, and Professor of Pathology.

In 2003, he moved the PGD aspects of his work into the Genesis Genetics Institute where the diagnostic aspects of PGD are provided to the most respected reproductive centers all around the world. Able to test for hundreds of genetic diseases, the Institute assists thousands of couples reach their dream of building a healthy family.

EXHIBIT J

Morganstern-Grossbaum results – 07/19/2004

Patient: Chaya Morganstern-Grossbaum – carrier - Exon 11, G542X Nt1756g>t
Partner: Menachem Grossbaum – carrier - Exon 10, dF508Nt1652 delCTT

Locus ID: 1080 Chromosome: 7q31.2 Gene: CFTR
OMIM: 602421

Biopsy done 7/17/2004 – began 10 am EDT, completed 11 am EDT
Quality is 1-4, where 1 is best
20 total tubes – 10 cells, 10 blanks

Sample	Quality	CF 10	CF 11	Call
2	2-8c	No deletion	T only	Possibly affected – ADO paternal
3	2-3c	No amp	No amp	No molecular signal
4	2-4c	No amp	G	Carrier at worst
7	2-7c	No amp	G	Carrier at worst
8	2-8c	No deletion	G/T	Carrier maternal – OK for transfer
9	2-4c	No amp	No amp	No molecular signal
10	2-4c	No deletion	G/T	Carrier maternal – OK for transfer
13	2-4c	No amp	G	Carrier at worst
14	2.-7c	No amp	No amp	No molecular signal
15	2-4c	No amp	G	Carrier at worst
CG		No deletion	G/T	Control – as expected
MG		Het. deletion	G	Control – as expected

Note: For sample 2, since only the mutant maternal allele was observed, it is possible that the paternal allele also dropped out of CF 10, and could be affected.

All controls and media blanks worked as expected. These data are very clear. All media blanks showed no evidence of exogenous DNA contamination.

Electronically signed,

Mark Hughes, M.D. Ph.D.